

CHAPTER 39

STATE BOARD OF PHARMACY

Authority

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

Source and Effective Date

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

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 39, State Board of Pharmacy, expires on December 13, 2004. See: 36 N.J.R. 3345(a).

Chapter Historical Note

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

Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989.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

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

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

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SUBCHAPTER 1. GENERAL PROVISIONS

13:39-1.1 Purpose and scope

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

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

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

Case Notes

Violations of N.J.A.C. 13:39-8.14(b)2, 10 and 13 found as controlled substances records were improperly kept, misbranded drugs were in

pharmacy and drugs were improperly stored, respectively; penalties (also cited as N.J.A.C. 13:39-8.12). New Jersey State Bd. of Pharmacy v. Yanuzzi, 4 N.J.A.R. 489 (1981).

13:39-1.2 Definitions

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

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

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

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

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

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

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

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

“Drug or medicine” means:

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

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

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

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

“Legend drug or device” means any drug or device that:

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

2. Requires a prescription or order by an authorized prescriber.

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

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

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

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

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

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

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

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

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

Inserted “Address of record”; in “Legend drug or device”, rewrote 1; rewrote “Licensed practitioner”; and in “Registered pharmacist” or “pharmacist”, substituted a reference to licenses for a reference to certificates, and substituted a reference to the current license renewal period for a reference to the current registration period.

13:39-1.3 Fee schedule

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

1. For pharmacists as follows:	
i. Application for registration	\$125.00.
ii. Examination: \$50.00 plus the cost of the North American Pharmacist Licensure Examination (NAPLEX).	
(1) Multistate Jurisprudence Pharmacy Examination (MJPE)	60.00.
iii. Reciprocal fee	125.00.
iv. Reinstatement of licensure	225.00
	plus application fee.
v. Initial licensure fee	
(1) If paid during the first year of a biennial renewal period	140.00.
(2) If paid during the second year of a biennial renewal period	70.00.
vi. Biennial license renewal	140.00.
vii. Replacement biennial license	25.00.
viii. Transfer of grades	125.00.
ix. Late renewal fee	100.00.
x. Replacement wall license	40.00.
xi. Continuing education review fee	10.00.
xii. Continuing education program 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 renewal	175.00.
(3) Change of ownership	275.00.
(4) Change of location	275.00.
ii. Replacement permit certificate	25.00.
iii. Replacement wall permit	25.00.
iv. Late renewal fee	100.00.

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

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

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

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

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

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".

13:39-1.4 Payment of penalties

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

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

13:39-1.5 Hearings

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

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

SUBCHAPTER 2. APPLICANT QUALIFICATIONS AND EXAMINATIONS REQUIREMENTS**13:39-2.1 Examinations; grades**

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

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

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

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

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

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

13:39-2.2 Education requirements

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

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

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

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

Recodified from N.J.A.C. 13:39-2.1 and amended by R.1999 d.214, effective July 19, 1999.

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

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

13:39-2.3 Application to be filed

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

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

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

Changed filing deadline from 60 to 30 days.

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

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

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

13:39-2.4 (Reserved)

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

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

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

13:39-2.5 (Reserved)

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

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

Section was "Proof of citizenship".

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

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

Section was "Language comprehension requirement".

13:39-2.6 (Reserved)

Recodified to N.J.A.C. 13:39-2.7 by R.1999 d.214, effective July 19, 1999.

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

13:39-2.7 Age requirement

An applicant who is not of legal age, that is, the age of majority in the State of New Jersey, but who has otherwise met the application requirements, with the exception of the internship requirement, may be admitted to the NAPLEX and MJPE examinations; however, the applicant shall not **be eligible for licensure until attaining legal age.**

Recodified from N.J.A.C. 13:39-2.6 and amended by R.1999 d.214, effective July 19, 1999.

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

Substituted a reference to NAPLEX and MJPE examinations for a reference to written examinations. Former N.J.A.C. 13:39-2.7, Proof of character, recodified to N.J.A.C. 13:39-2.8.

13:39-2.8 Proof of character

(a) An applicant for the NAPLEX and MJPE examinations shall submit, in advance, an application containing evidence of good moral character which is an ongoing requirement for licensure, and evidence that he or she:

1. Is not a chronic or persistent inebriate;
2. Is not addicted to the use of any controlled dangerous substance or other habit-forming drug;
3. 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;
4. Has not been convicted of violating the provisions of any law relating to the sale of liquors;
5. Has not been convicted of violating any law relating to the practice of pharmacy;
6. Has not been convicted of a crime involving moral turpitude; and
7. Has not had his or her license or, if a permit holder, his or her permit, suspended or revoked in the last five years as a result of any administrative or disciplinary proceedings in this or any other jurisdiction which proved 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.

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

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

Recodified from N.J.A.C. 13:39-2.7 and amended by R.1999 d.214, effective July 19, 1999.

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

In (a), substituted a reference to NAPLEX and MJPE examinations for a reference to written examinations in the introductory paragraph. Former N.J.A.C. 13:39-2.8, Proof of identity of applicant, recodified to N.J.A.C. 13:39-2.9.

13:39-2.9 Proof of identity of applicant

An applicant for the NAPLEX and MJPE examinations must submit to the Board 30 days in advance of the date of the written examination a passport photograph mounted on a document to be supplied by the Board requesting certain identification information.

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

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

Submission deadline changed from 60 to 30 days in advance.

Recodified from N.J.A.C. 13:39-2.8 and amended by R.1999 d.214, effective July 19, 1999.

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

Substituted a reference to NAPLEX and MJPE examinations for a reference to written examinations, and substituted a reference to passport photographs for a reference to bust photographs. Former N.J.A.C. 13:39-2.9, Alleged violations of the Pharmacy Act, recodified to N.J.A.C. 13:39-2.10.

13:39-2.10 Alleged violations of the Pharmacy Act

If an applicant for any Board examination is being investigated for any alleged violation of the Pharmacy Act, N.J.S.A. 45:14-1 et seq., the Board in its discretion may deny the applicant the opportunity to take the examination.

Recodified from N.J.A.C. 13:39-2.9 and amended by R.1999 d.214, effective July 19, 1999.

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

Substituted "being investigated for" for "involved in" following "examination is". Former N.J.A.C. 13:39-2.10, Written examinations; grades, recodified to N.J.A.C. 13:39-2.1.

SUBCHAPTER 3. LICENSURE OF PHARMACISTS**13:39-3.1 License**

An applicant who has successfully passed all Board examinations shall receive an authorization signed by the Executive Director of the Board granting the applicant the right to practice pharmacy in the State of New Jersey until such time as an initial license may be issued.

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

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

Substituted a reference to the Executive Director for a reference to the Secretary, and substituted a reference to initial licenses for a reference to original certificates of registration.

13:39-3.2 Duplicate license

A duplicate license may 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 original

license or upon return of the damaged original license to the Board.

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

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

13:39-3.3 Change of name

If a registered pharmacist legally changes his or her name, the name change shall be recorded in the Board's records. The registered pharmacist shall submit original proof of the change of name or a certified copy of the court order or marriage certificate which will be retained by the Board. When a duplicate license is issued, the original license must be returned for cancellation along with the required fee as prescribed in N.J.A.C. 13:39-1.3.

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

Substituted references to licenses for references to certificates in the last sentence.

13:39-3.4 Change of address of record

A registered pharmacist shall notify the Board in writing of any change in his or her address of record within 30 days.

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).

Substituted a reference to addresses of record for a reference to home addresses.

13:39-3.5 Certification of records

A certification that the license of a registered pharmacist is in good standing shall be supplied by the Board upon request.

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

13:39-3.6 Reproduction of original license prohibited

The original wall license, biennial license or wallet-sized license issued by the Board to any pharmacist 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. 13:39-3.16.

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

13:39-3.7 Limitation of reciprocal licensure

(a) Reciprocal licensure of out-of-State pharmacists shall be limited to those pharmacists who have been duly licensed in mutually reciprocating states.

(b) Applicants who have graduated from pharmacy schools which have not been accredited by the American Council on Pharmaceutical Education but who have been licensed by the District of Columbia, a reciprocating state or a United States territory shall be eligible for transfer of licensure if the Board is satisfied that the licensing procedures applicable to graduates of non-accredited schools in a state of licensure are equivalent to the Board's standards for licensure at the time initial licensure was obtained.

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

In (a), substituted a reference to licensure for a reference to registration; and rewrote (b).

13:39-3.8 Basic requirement for transfer of licensure

An applicant for reciprocal licensure in the State of New Jersey shall hold a current, valid license in any state of licensure, including the District of Columbia and territories of the United States, that has a standard for initial licensure that is equivalent to the standard of licensure that was in effect in the State of New Jersey at the time initial licensure was obtained.

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

13:39-3.9 Out-of-State practice requirement for transfer of license from a mutually reciprocating state

(a) An applicant for reciprocal licensure in the State of New Jersey shall be in good standing with any state in which the applicant is licensed and must have:

1. Practiced in pharmacy for at least 1000 hours within the two years immediately prior to application; or
2. Served a pharmacy practicum in New Jersey, in the presence of a New Jersey registered pharmacist approved by the Board as a certified preceptor pursuant to N.J.A.C. 13:39-8.2, of not fewer than 500 hours within the one year immediately prior to application.

Amended by R.1992 d.235, effective June 1, 1992.
See: 24 N.J.R. 553(a), 24 N.J.R. 2062(a).
Revised section.

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

In (a), substituted a reference to licensure for a reference to registration in the introductory paragraph, and inserted "as a certified preceptor pursuant to N.J.A.C. 13:39-8.2" following "Board" in 2.

13:39-3.10 Clear record of law observance

Eligibility for reciprocal licensure shall be denied any person against whom there are pending any formal charges for any violations of the laws governing the practice of pharmacy or the dispensing of controlled dangerous substances, alcohol or other regulated drugs, or who has been convicted of any crime within the past five years. All applicants for transfer of licensure shall meet the character requirements outlined in N.J.A.C. 13:39-2.8.

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

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

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

13:39-3.11 Foreign graduates

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

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

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

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

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

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

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

Rewrote the section.

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

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

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

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

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

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

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

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

13:39-3.13 Preliminary application

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

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

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

Substituted a reference to licensure for a reference to registration.

13:39-3.14 Multistate Jurisprudence Pharmacy

Examination: reciprocal licensure

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

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

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

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

Rewrote the section.

13:39-3.15 Biennial registration renewal

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

(b) The renewal application shall list the name, address of record, original license number, places and hours of employment, number of continuing education credits completed pursuant to the provisions of N.J.A.C. 13:39-3A, and other information as requested by the Board.

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

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

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

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

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

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

Amended by R.2003 d.130, effective March 17, 2003.

See: 34 N.J.R. 1089(a), 35 N.J.R. 1433(a).

Rewrote (b).

13:39-3.16 Duplicate renewal license

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

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

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

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

13:39-3.17 Reinstatement in good standing

(a) If a registered pharmacist permits his or her license to lapse for a period of less than five years through a failure to renew his or her license, the license may be brought into

good standing through payment as per N.J.A.C. 13:39-1.3(a)liv and vi of the reinstatement fee, the current and lapsed renewal fee(s) and any outstanding penalties and upon submission of proof of identity and the filing of an application to be obtained from the Board. An applicant for reinstatement shall also submit proof of satisfaction of continuing education requirements as provided in N.J.S.A. 45:14-11.11.

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

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

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

Rewrote (a) and (b).

13:39-3.18 Registered pharmacist-in-charge

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

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

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

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

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

1. Employment and supervising personnel in a prescription department or pharmacy department;
2. Maintaining accurate records of all prescription medication received and dispensed;

3. Ensuring that medication dispensed conforms with the prescription received;

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

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

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

7. Ensuring that all dispensed medication is properly labeled;

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

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

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

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

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

13. Ensuring compliance with all statutes, rules and regulations governing the practice of pharmacy.

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

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

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

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

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

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.

SUBCHAPTER 3A. CONTINUING EDUCATION

Authority

N.J.S.A. 45:14-11.12 and 45:1-15.1.

Source and Effective Date

R.2003 d.130, effective March 17, 2003.

See: 34 N.J.R. 1089(a), 35 N.J.R. 1433(a).

13:39-3A.1 Continuing education credit hour requirements

(a) Each applicant for biennial license renewal shall complete a minimum of 30 credits of continuing education during the preceding biennial period, except that the Board shall not require completion of continuing education credits for an applicant's initial license renewal. At least 10 of the continuing education credits shall be obtained through didactic instruction. For purposes of this paragraph, "didactic instruction" means in-person instruction and may include telephonic or electronic instruction that is interactive, but shall not include videotaped instruction.

(b) Ten credits of continuing education may be carried over into a succeeding biennial period only if such credits were earned during the last six months of the preceding biennial period and were not previously reported.

13:39-3A.2 Criteria for continuing education credit

(a) A licensee may obtain continuing education credit from the following categories:

1. Programs or courses offered by American Council of Pharmaceutical Education approved providers;
2. Programs and courses that have received prior Board approval pursuant to N.J.A.C. 13:39-3A.6;
3. Graduate course work relevant to the practice of pharmacy, taken at an accredited college or university, beyond that required for professional licensure;
4. Participation in teaching and/or research appointments;
5. Participation as a preceptor in externship programs;
6. Participation as a preceptor in internship programs; and
7. Publication of an article related to the practice of pharmacy in a peer-reviewed professional journal.

13:39-3A.3 Continuing education credit hour calculations

(a) Credit for continuing education shall be granted as follows for each biennial license period:

1. Attendance at approved programs or courses shall be granted one credit for each hour of attendance. Credit shall not be granted for programs or courses which are less than one contact hour in duration, which is defined as 50 minutes of actual attendance in a program or course of study. One half credit shall be granted for each 30 minute segment of a program or course that is more than one contact hour in duration. Completion of an entire program or course is required in order to receive any continuing education credit for the program or course.
2. Successful completion of graduate course work related to the practice of pharmacy at an accredited college or university beyond that which is required for profession-

al licensure shall be granted three continuing education credits for each course credit awarded.

3. Teaching and research appointments related to the practice of pharmacy shall be granted three continuing education credits for each new program or course taught or subject matter researched by a licensee, to a maximum of six credits. "New," in this paragraph, means a program, course or subject matter which the licensee has never taught or researched before in any educational or practice setting. A licensee who is employed as a teacher and/or as a researcher on a full-time basis shall not be eligible to obtain continuing education credit for such activities.

4. Participation as a preceptor in an externship program, upon prior approval by a college of pharmacy, shall be granted three continuing education credits per student to a maximum of six credits.

5. Participation as a preceptor in an internship program shall be granted three continuing education credits per 160 hours of work performed by the intern(s) and supervised by the licensee, to a maximum of six credits.

6. Publication of an article related to the practice of pharmacy in a peer-reviewed professional journal shall be granted three continuing education credits per article to a maximum of six credits.

(b) The Board shall not grant credit for, or approve as a component of a continuing education program, participation in the routine business portion of any meeting of a pharmaceutical organization or any presentation that is offered to sell a product or promote a business enterprise.

13:39-3A.4 Continuing education credit hour reporting procedure

(a) A licensee shall specify on his or her application for biennial license renewal the number of continuing education credits completed. Falsification of any information contained in the renewal application may result in an appearance before the Board and the assessment of penalties and/or license suspension pursuant to N.J.S.A. 45:1-21 et seq.

(b) A licensee shall maintain all documentation concerning the completion of continuing education requirements for a period of five years from the completion of the credit hours and shall submit such documentation to the Board upon request. Such documentation shall consist of:

1. For programs offered by American Council of Pharmaceutical Education approved providers, a certificate of completion from the course or program;
2. For programs and courses approved by the Board, the sponsors' written verification of attendance;
3. For teaching or research appointments in an academic setting, a statement from the chairperson of the department verifying completion of the assignment;

4. For research appointments in an industrial setting, a statement from the project coordinator verifying completion of the assignment;

5. For participation as a preceptor in an externship program, a certificate from the college of pharmacy;

6. For participation as a preceptor in an internship program, a certificate from the Board; and

7. For publications in a peer-reviewed professional journal, submission of the published article.

(c) The Board shall audit licensees on a random basis at the end of each biennial period to determine compliance with continuing education requirements.

13:39-3A.5 Waiver of continuing education requirements

(a) The Board may waive continuing education requirements on an individual basis for reasons of military service, hardship, illness or disability.

(b) A licensee seeking a waiver of continuing education requirements shall apply to the Board in writing and set forth with specificity the reasons for requesting the waiver. The licensee shall also provide the Board with such additional information as the Board may request in support of the application for waiver.

(c) A waiver of continuing education requirements granted pursuant to this section shall be effective only for the biennial period in which such waiver is granted. If the condition(s) which necessitated the waiver continues into the next biennial period, a licensee shall apply to the Board for a renewal of such waiver for the new biennial period.

13:39-3A.6 Responsibilities of continuing education sponsors

(a) A continuing education sponsor shall receive prior Board approval for a program or course if the sponsor provides, in writing on a form provided by the Board, information which demonstrates that the program or course meets the following requirements:

1. The program or course is offered in a subject matter relevant to the practice of pharmacy;
2. The program or course is at least one contact hour in length; and
3. The program or course is conducted by a qualified instructor or discussion leader who submits a curriculum vitae and who is:
 - i. A pharmacist with a B.S. in Pharmacy or a Pharm.D. with at least five years of experience;

ii. A pharmacist with a B.S. in Pharmacy or a Pharm.D. with expertise in the program or course subject area;

iii. A pharmacist with a B.S. in Pharmacy or a Pharm.D. who is certified by a nationally recognized board or association; or

iv. A licensed health care professional who demonstrates special expertise in the lecture subject area.

(b) A continuing education sponsor may request approval for a program or course conducted by an individual who possesses expertise in a subject area relevant to the practice of pharmacy, provided that the program or course to be conducted by that individual satisfies the requirements of (a)1 and 2 above.

(c) Applications for pre-approval of continuing education programs or courses shall be submitted by the continuing education sponsor on a form provided by the Board at least 45 days prior to the date the program or course is to be offered. Incomplete applications shall be returned to the sponsor.

(d) The Board shall approve only such continuing education programs and courses as are available and advertised on a reasonable nondiscriminatory basis to all persons licensed to practice pharmacy in the State. The Board shall maintain a list of all approved programs and courses at the Board office and shall furnish the list to licensees upon request.

(e) A continuing education sponsor shall not make substantive changes to an approved program or course, such as a change in program or course content or instructor, without prior Board approval.

(f) The continuing education sponsor shall monitor attendance at, or ensure completion of, each approved program or course and furnish to each enrollee a verification of attendance which shall include at least the following information:

1. The title, date and location of the program or course offering;
2. The name of the program or course presenter;
3. The name and certificate number of the program or course presented;
4. The number of continuing education credits awarded; and
5. The name, address, telephone number and signature of the sponsor, or if the sponsor is an association or organization, the signature of an officer or responsible party of the association or organization.

(g) The continuing education sponsor shall submit the fee set forth at N.J.A.C. 13:39-1.3(a)1xii for each submission of program or course offerings.

(h) The continuing education sponsor shall maintain a list of all attendees who completed each approved program or course for a period of five years from the date the program or course was offered.

13:39-3A.7 Monitoring of continuing education programs or courses

A Board member or a Board representative may monitor an approved program or course without prior notification to the continuing education sponsor.

SUBCHAPTER 4. PHARMACY PERMITS

13:39-4.1 Issuance of permits

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

13:39-4.2 Display of permits

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

13:39-4.3 Death of owner or partner

In the case of death of an individual owner or a partner, the permit issued to the deceased owner or to the partnership is terminated and shall be returned to the Board pursuant to N.J.A.C. 13:39-4.8. If the operation of the pharmacy is to be continued, the estate or heirs of the deceased partner and/or the remaining partners shall apply immediately for a new permit on a form prescribed and furnished by the Board and pay a fee pursuant to N.J.A.C. 13:39-1.3.

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

Substituted "is terminated and shall be returned to the Board pursuant to N.J.A.C. 13:39-4.8" for "becomes null and void" at the end of the first sentence.

13:39-4.4 Change of ownership

Whenever there is any change in ownership of the business entity holding a permit to operate a pharmacy, the new ownership of such entity shall apply for a new permit on a form prescribed and furnished by the Board and pay a fee pursuant to N.J.A.C. 13:39-1.3. The new owner of such entity shall not operate a pharmacy under an existing permit for more than 60 days following a change in ownership. Before a permit may be issued to the new owner of the business entity, the Board shall inspect and approve, as in compliance with this chapter, the fixtures, equipment and inventory of the pharmacy, and shall require evidence of the transfer of ownership and an inventory of controlled substances being transferred to the new owner(s).

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

Rewrote the section.

13:39-4.5 Change of corporate officers or stockholders of public companies

If there is a change of registered agents or officers or a change of stock ownership involving 10 percent or more of the outstanding stock, the corporation shall file an affidavit with the Board within 30 days indicating the changes that have taken place and any other information requested by the Board.

13:39-4.6 Change of location; remodeling of premises

(a) Whenever a pharmacy or licensed establishment changes location, the pharmacy or licensed establishment shall apply for a new permit on a form prescribed and furnished by the Board. The pharmacy or licensed establishment shall pay a fee for the new permit pursuant to N.J.A.C. 13:39-1.3. The permit holder shall not operate a pharmacy under an existing permit for more than 60 days following a change of location. Before a permit may be issued to the permit holder for the new location, the Board shall inspect and approve, as in compliance with this chap-

ter, the premises, fixtures, equipment and inventory of the new location.

(b) Prior to the remodeling of a pharmacy, pharmacy department or licensed establishment, where such remodeling entails a physical change of location of the prescription area within the premises or a change of the physical specifications of the licensed premises or the compounding area, it shall be necessary to notify the Board at least 30 days in advance on a form prescribed by the Board. The permit holder shall not operate a pharmacy under an existing permit for more than 60 days following the remodeling of a pharmacy. Within 60 days of the remodeling, the Board shall inspect and approve, as in compliance with this chapter, the premises, fixtures, equipment and inventory of the remodeled pharmacy.

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

Rewrote (a); and in (b), added the second and third sentences.

13:39-4.7 New pharmacies; eligibility and application

(a) A permit application shall be submitted to the Board by every person or corporation desiring to operate a new pharmacy. Such application shall be made on a form furnished by the Board.

(b) The permit application shall indicate the exact intended location and plan or physical arrangement of the proposed pharmacy area and shall indicate any premises contiguous to but not necessarily a part of the pharmacy.

(c) The permit application shall bear the exact trade name, if any; the corporate names, if any; the name and addresses of the owners and operators, if a sole proprietorship or partnership; the names and addresses of all officers and stockholders and the names and addresses of all principles duly licensed to write prescriptions if the pharmacy is a non-publicly held corporation; and the names and addresses of the officers, if a publicly held corporation.

(d) The permit application shall include the name of the registered pharmacist-in-charge who shall be a registered pharmacist in good standing in the State of New Jersey.

(e) No person or other business entity shall be eligible for a new permit or a renewal thereof who is not of high moral character or against whom there is pending any indictment or any alleged violation of local, state or Federal law pertaining to the practice of pharmacy or the dispensing of controlled dangerous substances or any drug under N.J.S.A. 24:21-2.

(f) A person submitting an application may be interviewed by the Board to review his or her qualifications and eligibility.

(g) Before a permit may be issued to an applicant, the Board shall inspect and approve, as in compliance with this

chapter, the premises, fixtures and equipment of the new pharmacy.

(h) Upon approval of the permit application, the Board shall issue a permit number that will allow the applicant to place prescription legend drugs in stock.

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 (d), substituted a reference to registered pharmacists-in-charge for a reference to pharmacists-in-charge; inserted a new (g); and recodified former (g) as (h).

13:39-4.8 Discontinued pharmacies

(a) Whenever a pharmacy is terminated by suspension, retirement or death of the owner, sale or other cause including insolvency, all drug signs shall be removed from both the inside and outside of the discontinued pharmacy, and the permit shall be returned to the Board for cancellation within 30 days of the closing. Prescription records and other information may be requested by the Board as outlined in N.J.A.C. 13:39-5.6.

(b) Whenever a pharmacy is to be discontinued, it shall be the responsibility of the permit holder to immediately notify by telephone the State Board of Pharmacy, the Drug Control Program in the State Department of Health and the Drug Enforcement Administration of the proposed closing at least 15 days beforehand, followed by a letter in writing to those agencies. All medication (both prescription legend and controlled drugs) shall remain on the licensed pharmacy premises with all licenses and registrations in effect until such medications are disposed of in the manner prescribed by the above agencies.

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), changed N.J.A.C. reference.

13:39-4.9 Business hours

(a) All pharmacies shall be kept open for the transaction of business at least 40 hours per week and at least five days per week.

(b) If any changes are made in the opening or closing hours of a pharmacy or other Board-licensed establishment, the Board office shall be notified in writing of these changes within 30 days.

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

13:39-4.10 Duplicate permit

A duplicate permit may be issued by the Board upon payment of a fee pursuant to N.J.A.C. 13:39-1.3 and submission of an affidavit describing the loss or destruction of the permit originally issued, or upon return of the damaged permit.

13:39-4.11 Change of name

(a) A change in the name of a pharmacy or other Board-licensed establishment shall be made upon the submission to the Board for approval of the new name and of prescription labels bearing the new name.

(b) An amended permit bearing the new name may be obtained upon return of the original permit to the Board for cancellation and payment of the permit fee as prescribed in N.J.A.C. 13:39-1.3.

13:39-4.12 Reproduction of permits

Any permit issued by the Board for the operation of a pharmacy or other board-licensed establishment, with the exception of single copies to State agencies shall not be printed, photographed, photostated, duplicated or reproduced by any other means either in whole or in part, without the express authorization of the Board.

13:39-4.13 Certification of records

A certification of any of the information not obtained by the Board on a confidential basis, which appears in the Board records and concerns the ownership or registration of a pharmacy or other Board-licensed establishment, will be supplied only upon written request and payment of a certification fee as prescribed in N.J.A.C. 13:39-1.3.

13:39-4.14 Contract pharmaceutical services

An institutional permit is required for any area within an institution where drugs are stored, manufactured or compounded and which is serviced by an outside vendor that performs pharmaceutical services as defined in N.J.A.C. 13:39-1.2.

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

13:39-4.15 Retail permit; prescription department or pharmacy department

(a) If the area for which a pharmacy permit is sought is less than the total store area of the enterprise, the area subject to permit shall be known as the "Prescription Department" or "Pharmacy Department".

(b) The holder of a permit to operate a prescription or pharmacy department and the registered pharmacist-in-charge of the department shall be subject to the following additional requirements:

1. The prescription or pharmacy department shall be constructed so as to enable the closing off and securing of the department from the main store area. The department shall be separated from the main store area by a secured barrier or partition extending from the floor or fixed counter to the ceiling of either the department or main store and attached thereto. Any entrance to the prescription or pharmacy department shall be capable of being locked and connected to a security device or other Board approved security system.

2. The registered pharmacist on duty shall be responsible for keeping the prescription department secure and locked and the alarm system turned on at all times when he or she does not have full vision or control of the department or when he or she is not present within the department. Only the registered pharmacist-in-charge of the licensed premises shall be responsible for the security of the keys to the department.

3. No prescription shall be accepted or prescription medication supplied to anyone during the period that a registered pharmacist is not present within the department.

4. All medications requiring supervision of a pharmacist, including dispensed medication, shall remain within the confines of the department when the pharmacist is not in the prescription department.

5. The hours that the department is open shall be posted in plain view at the entrance to the department and at the public entrance to the enterprise containing the department.

6. When the enterprise in which the department is located maintains different store hours from the pharmacy or prescription department, all advertising, announcements, signs or statements indicating store hours and the presence of the pharmacy or prescription department shall clearly and distinctly indicate the hours that the department is open.

7. The prescription department shall have a published telephone number different from that of the establishment in which the department is located. No extensions of this phone shall be located outside the department.

8. The name of registered pharmacist-in-charge shall be posted so as to be visible from outside of the department. The telephone number of the registered pharmacist-in-charge shall be available in the office of the manager of the establishment.

9. There shall be provided a secure area for the receiving of prescription drugs from suppliers. No prescription drug shall be accepted from any supplier during the hours the prescription or pharmacy department is closed unless adequate security for the storage of department shipments has been provided and approved by the Board.

10. If a drop-off device is utilized for prescriptions it shall be of a one-way, irretrievable design.

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 (b), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge in 2 and 8.

13:39-4.16 Permits; specialized permits

(a) The Board may issue a special permit, wherein the type of service is of a limited nature. The permit so issued,

being based on special conditions of use imposed by the Board, may necessitate the waiver of certain rule requirements.

(b) Specialized permits shall pertain to pharmacies providing specific services as may be necessary and proper to efficiently meet a limited public need for pharmaceutical services. An applicant for any specialized pharmacy permit shall provide the Board with an application and a policy and procedure manual which sets forth a detailed description of the type of specialized pharmacy services to be provided within the pharmacy practice. The policy and procedure manual shall also contain detailed provisions which ensure the protection of the public welfare as determined by the Board.

13:39-4.17 Steering prohibited

It shall be unlawful for a pharmacist or a pharmacy permit holder to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions, or with any health care facility for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom of choice to select a pharmacy.

13:39-4.18 Responsibilities of pharmacists and permit holders

(a) All pharmacists and all permit holders are responsible for compliance with all the rules, regulations and laws governing the practice of pharmacy.

(b) Any pharmacist and any permit holder may be held liable for violations of the Act and these rules and may be subject to disciplinary action.

SUBCHAPTER 5. PRESCRIPTIONS

13:39-5.1 Imprinted prescription blanks

No prescriber's prescription blanks shall bear the imprint of the name of any pharmacy or other licensed premises or bear the name and address of any person registered under N.J.S.A. 45:14-1 et seq.

13:39-5.2 Lack of directions on original prescription

(a) 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.

(b) When, in the judgment of the pharmacist, directions to the patient or cautionary messages are necessary, either for clarification or to ensure proper administration of the medication, the pharmacist may add such directions or cautionary messages to those indicated by the prescriber on the original prescription.

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).

13:39-5.3 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).

13:39-5.4 Approval of FDA necessary

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 an approved NDA, ANDA, INDA or other Federal Food and Drug Administration approval.

Cross References

Exception, see N.J.A.C. 13:39-9.5.

13:39-5.5 Copies of prescriptions; transfers

(a) Copies of prescriptions issued directly to the patient by the pharmacy where the medication was dispensed, pursuant to the receipt of the prescription, shall state in letters at least equal in size to those describing the medication dispensed, the underlined statement: "COPY—FOR INFORMATION ONLY." A pharmacist shall immediately comply with the patient's request for copies of prescriptions that are marked: "COPY—FOR INFORMATION ONLY."

(b) Presentation of a prescription label or a prescription marked "COPY—FOR INFORMATION ONLY" shall be for information purposes only and have no legal status as a valid prescription order. The recipient pharmacist of such copy or prescription label shall contact the prescribing practitioner or transferor pharmacy and obtain all information required by (c)2 below for authorization to dispense the prescription, which is the same as obtaining an original prescription order.

(c) A copy of a prescription may be transferred by telephone or electronic transfer by pharmacists between pharmacies for the purpose of refill dispensing provided that:

1. The transferor pharmacist invalidates the prescription on file as of the date the copy is transferred by writing "VOID" on its face, and records on the back of the invalidated prescription order that a copy has been issued, the date of issuance of such copy, to which pharmacy and pharmacist, and the initials of the pharmacist issuing the transferred prescription order.

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

- i. The name, address and original prescription number of the pharmacy from which the prescription was transferred;
- ii. The name of the transferor pharmacist;
- iii. All information constituting a prescription order, including the following:

(1) Date of issuance of original prescription;

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

(3) Complete refill record from original prescription;

(4) Date of original dispensing;

(5) Number of valid refills remaining.

3. The transferee pharmacist informs the patient that the original prescription has been cancelled at the pharmacy from which it was obtained.

(d) When a copy of a prescription is issued by telephone, refill authorizations shall be cancelled on the original prescription and the fact that a copy has been issued shall be noted on the original prescription along with the date the copy was issued. Two or more permit holders may establish a common electronic filing system to maintain required dispensing information and the required documentation, pursuant to N.J.A.C. 13:39-5.6.

(e) When a patient, or his or her properly authorized representative, requests the transfer of a valid prescription between pharmacies, a pharmacist shall immediately comply with the patient's request. "Properly authorized representative" means a patient's spouse, next of kin, legal guardian, attorney or third party insurer where permitted by law.

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).

13:39-5.6 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 or extern shall place his or her signature or readily identifiable initials on the face of the original prescription. In using an electronic data processing system, the initials of the pharmacist responsible for the filled prescription shall also be recorded.

(b) A registered pharmacist who refills a prescription shall place his or her signature or readily identifiable initials on the reverse side of the original prescription next to the date of the refill and the amount dispensed in refilling the prescription if it is different from the original amount prescribed. In using an electronic data processing system, the identical refill information shall also be recorded.

(c) A record identifying such initials with the signature and name and address of the pharmacist shall be maintained for a period of five years after the termination of employment of said pharmacist.

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

(e) Except when they are kept in a separate file, prescriptions for all controlled substances listed in schedules III, IV and V shall be stamped in red ink in the lower right corner with the letter "C" no less than one-inch high.

(f) Prescriptions for all controlled substances listed in schedules III, IV and V shall be maintained in a single file separate from all other prescriptions, unless an electronic data processing system is utilized which meets the requirements of (i) below. If such an electronic data processing system is utilized, prescriptions for all substances listed in schedules III, IV and V shall be 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.

(g) If an electronic data processing system is utilized in connection with the dispensing of medication and the required recording of prescription information, a means ac-

ceptable to the Board shall be utilized to identify the pharmacist or intern or extern dispensing the medication.

(h) In using an electronic data processing system, the pharmacist in charge shall maintain a document log. The document log shall be maintained at the pharmacy for a period of five years after the date of the last entry. The five years of record information, including refills, shall be kept in such a manner as to be sight-readable within two weeks. The most recent one year of record information shall be immediately retrievable.

(i) In using an electronic data processing system, the system shall have the capability of producing sight-readable documents of all original and refilled prescription data, and, in addition, the number of refills authorized by the prescriber for a period of not less than five years. Five years of record information shall be maintained in such a manner so as to be sight-readable within two weeks. The most recent one year of record information shall be immediately reviewable on-line and available in printed form within three business days. The term "sight-readable", as it appears in all rules of the Board, shall mean that the Board or Attorney General shall be able to examine and read the record of information. During the course of an on-site inspection, the record may be read from a cathode ray tube (CRT), microfiche, microfilm, hard copy printout or other Board acceptable method. For the purpose of administrative proceedings before the Board, records shall be provided in a paper printout form.

(j) Initials and/or access code number(s) of the dispensing pharmacist and intern or extern, if applicable, 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 dispensing pharmacist at the time of dispensing are prohibited.

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).

13:39-5.7 Availability of records upon termination of business

(a) Where a pharmacy ceases operation as the result of a suspension, retirement or death of the owner, sale or other cause including insolvency, the licensee, or the one responsible for supervising the disposition of the practice, shall make every effort to notify patrons of their right to retrieve currently valid prescriptions and the location of the prescriptions and profile records for a six-month period following notice, using all of the following methods:

1. Notification in writing to the Board;
2. Publication, once weekly for two successive weeks in a newspaper whose circulation encompasses the major

area of the licensee's former practice, of a notice advising patrons of the right to retrieve their prescriptions and the location of the prescriptions for a six-month period following publication; and

3. A sign placed in the pharmacy location informing the patrons of the right to retrieve their prescriptions and the location of the prescriptions.

13:39-5.8 Prescriptions and medication orders transmitted by technological devices in an institution

(a) A pharmacist may, subject to the conditions set forth in this section, accept for dispensing a prescription or a medication order transmitted by a facsimile (FAX) machine or other technological device as approved by the Board.

(b) A registered pharmacist filling prescriptions under an institutional permit for employees of the institution and their dependents and for out-patients who are treated by staff members of the institution in their respective clinics, as permitted pursuant to N.J.S.A. 45:14-32, may accept for dispensing prescriptions for all substances other than Schedule II controlled dangerous substances which have been transmitted by technological device, under the following conditions only:

1. Before releasing to other than an in-patient of a health care facility, as defined in N.J.A.C. 13:39-9.1, any prescription medication for a controlled dangerous substance listed in Schedules III, IV or V, the pharmacist shall obtain and file the original signed prescription.

2. The pharmacist shall, within 24 hours, reduce to hard copy, that is, record in his or her handwriting or enter into a computer, all prescriptions received by technological device other than prescriptions for Schedules III, IV and V controlled dangerous substances and shall place the copy in the permanent prescription file records.

(c) A registered pharmacist who is authorized to fill inpatient medication orders, as defined in N.J.A.C. 13:39-9.1, in an institutional pharmacy may accept all inpatient medication orders, including orders for Schedule II substances, which have been transmitted by technological device. Medication orders for narcotic Schedule II controlled substances written for long-term care facility residents or hospice patients, which are transmitted by facsimile, shall serve as the original written medication orders, in accordance with the provisions of 21 C.F.R. 1306.11(d), (e), (f) and (g).

(d) Whenever a pharmacist has reason to question the accuracy or authenticity of a prescription or medication order transmitted by technological device, the pharmacist shall verify the transmission directly with the prescribing practitioner.

(e) It shall be deemed professional misconduct for a pharmacist to use a technological device in order to circumvent his or her responsibilities with regard to documenting, authenticating and verifying medication orders and prescriptions or in order to circumvent other standards of pharmacy practice.

(f) No licensee or permit holder registered under N.J.S.A. 45:14-1 et seq. shall under any circumstances provide a technological device to, or accept a technological device from, any practitioner licensed to write prescriptions.

(g) No licensee or permit holder shall enter into any agreement with an authorized practitioner which denies the patient the right to have his or her prescription transmitted by technological device to a pharmacy of the patient's choice.

New Rule, R.1992 d.166, effective April 6, 1992.

See: 23 N.J.R. 2469(a), 24 N.J.R. 1371(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 (c), added the last sentence.

Amended by R.2003 d.373, effective September 15, 2003.

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

In (b), deleted "at a retail pharmacy and a registered pharmacist" preceding "filling prescriptions".

13:39-5.8A 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 pre-

scriptions 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.

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

13:39–5.8B Electronically transmitted prescriptions

(a) A pharmacist may accept for dispensing an electronic prescription, consistent with the requirements of this section. For purposes of this section, "electronic prescription" means a prescription which is transmitted by a computer device in a secure manner, including computer to computer and computer to facsimile transmissions.

(b) A pharmacist shall not fill an electronic 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. If the electronic prescription is transmitted by the practitioner's authorized agent, the transmission shall include the full name and title of the agent.

(c) The permit holder shall ensure that the electronic system utilized to receive prescriptions shall have adequate security and system safeguards designed to prevent and detect unauthorized access, modification or manipulation of the prescriptions.

(d) The computer or device used to receive electronically transmitted prescriptions shall be located within the pharmacy prescription area.

(e) An electronic 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 a handwritten original signature and an NJPB shall not be required for the prescription.

(f) A pharmacist shall seek verbal verification of an electronic 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 an electronic prescription from a prescribing practitioner's authorized agent. A pharmacist shall not fill the electronic 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 an electronic prescription, or a record of an electronic 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 electronically, provided that the original signed prescription is presented to the pharmacist prior to the dispensing of the controlled substance. If permitted by Federal law, and in accordance with Federal requirements, an electronic prescription shall serve as the original signed prescription.

(i) A pharmacist may fill a prescription for a Schedule III, IV or V controlled substance transmitted electronically, provided that the pharmacist has obtained the original signed prescription, an oral prescription, or a facsimile prescription from the prescribing practitioner or the prescribing practitioner's authorized agent prior to the dispensing. If permitted by Federal law, and in accordance with Federal requirements, an electronic prescription shall serve as the original signed prescription.

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

13:39-5.9 Labeling

(a) The dispensed container for any product shall bear a permanently affixed label with at least the following information:

1. The name of the registered pharmacist-in-charge;
2. The pharmacy name and address;
3. The pharmacy telephone number;
4. The brand name or generic name;
 - i. If generic, the name of the manufacturer;
5. The date upon which prescription medication is dispensed;
6. A CDS cautionary label;
7. The patient name;
8. The initials of dispensing pharmacist;
9. The prescriber's name;
10. The prescription number;
11. Directions for use; and

12. The expiration date, if dispensed in any packaging other than the manufacturer's original packaging.

i. For purposes of this paragraph, "expiration date" means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container.

(b) In addition to the requirements set forth in (a) above, the dispense container for any product shall bear all auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional judgment of the dispensing pharmacist.

New Rule, R.1999 d.196 effective June 21, 1999.
See: 30 N.J.R. 4113(a), 31 N.J.R. 253(a), 31 N.J.R. 1618(a).

13:39-5.10 Procedures for centralized prescription handling

(a) The four component functions of handling a prescription are intake, processing, fulfillment and dispensing.

(b) Central prescription handling entails two or more licensed pharmacies sharing responsibility for performing the four component functions of handling a prescription.

(c) The following pharmacies may engage in central prescription handling: an intake or originating pharmacy; a central processing pharmacy; a central fill pharmacy; and a dispensing pharmacy. The four component functions of handling a prescription shall be performed by the following pharmacies:

1. An intake or originating pharmacy, which is a licensed pharmacy that received the patient's or prescribing practitioner's request to fill or refill a prescription. A central processing pharmacy or a central fill pharmacy, as delineated in (c)2 and 3 below, may be considered the intake or originating pharmacy if the prescription was transmitted by the prescribing practitioner directly to the centralized pharmacy as provided in N.J.A.C. 13:39-5.8A and 5.8B or if the patient requested the refill from that pharmacy;
2. A central processing pharmacy, which is a licensed pharmacy that engages in prescription review by performing functions that may include, but are not limited to, data entry, prospective drug review, refill authorizations, interventions, patient counseling, claims submission, claims resolution and adjudication;
3. A central fill pharmacy, which is a licensed pharmacy engaging in central prescription handling by filling and/or refilling prescriptions which includes the preparation and packaging of the medication; and

4. A dispensing pharmacy, which is a licensed pharmacy that receives the processed prescription and/or the filled or refilled prescription for dispensing to the patient or to the patient's authorized representative.

(d) Two or more of the licensed pharmacies delineated in (c) above may engage in central prescription handling provided:

1. Any or all of the pharmacies participating in central prescription handling have a contractual agreement to provide such services or have the same owner;

2. Prior to engaging in central prescription handling, all pharmacies that are parties to the central prescription handling obtain Board approval. The pharmacies shall make a single application to the Board, delineating the scope of practice of each pharmacy and the specific rules in this chapter with which each pharmacy shall comply;

3. An audit trail is maintained that records and documents the name(s) or other personal identifier(s) of the pharmacist(s) or pharmacy technician(s) and the component function(s) performed by each, at the time the functions are performed, for each step of prescription handling. The audit trail shall be maintained for not less than five years from the date the prescription is filled or refilled. 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;

4. The dispensed prescription for any product bears a permanently affixed label with at least the following information:

- i. The brand name or generic name, and if generic, the name of the manufacturer;
- ii. The strength of medication, where applicable;
- iii. The quantity dispensed;
- iv. The date upon which prescription medication is dispensed;
- v. A CDS cautionary label, where applicable and when permitted by law;
- vi. The patient name;
- vii. The prescriber name;
- viii. The prescription number;
- ix. Directions for use;
- x. The phrase "use by" followed by the product's use by date, if dispensed in any packaging other than the manufacturer's original packaging. For purposes of this paragraph, "use by date" means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container;

xi. All auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional judgment of the dispensing pharmacist; and

xii. The name, address and telephone number of any or all of the following:

- (1) The intake pharmacy;
- (2) The central processing pharmacy;
- (3) The central fill pharmacy; and/or
- (4) The dispensing pharmacy;

5. The patient name, the brand or generic name of the medication, and the directions for use appear in larger type, in a different color type, or in bolded type, in comparison to the other information required to appear on the label of the dispensed container pursuant to (d)4 above;

6. The patient is provided with written information, either on the prescription label or with the prescription container, that indicates which pharmacy to contact if the patient has any questions about the prescription or the medication. The written information provided to the patient shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service shall be available at no cost to the pharmacy's primary patient population;

7. All pharmacies that are to engage in central prescription handling maintain a common policies and procedures manual which designates who shall be responsible for each of the component functions of handling the prescription and for ensuring compliance with the Board rules set forth in this chapter. The policies and procedures manual shall also include maintenance of the audit trail required by (d)3 above. The policies and procedures manual shall be made available to the Board upon request;

8. All pharmacies that are to engage in central prescription handling share a common electronic file; and

9. All pharmacies that are to engage in central prescription handling are responsible for ensuring that the prescription has been properly filled.

(e) A prescription for a controlled substance may be filled or refilled by pharmacies engaging in central prescription handling when permitted by law, consistent with Federal requirements set forth at 21 C.F.R. §§ 1300 et seq.

New Rule, R.2004 d.380, effective October 4, 2004.
See: 36 N.J.R. 11(a), 36 N.J.R. 4480(a).

SUBCHAPTER 6. DISPENSING AND ADVERTISING DRUGS

13:39-6.1 Professional judgment in dispensing drugs

(a) The pharmacist shall have the right to refuse to fill a prescription if, in his or her professional judgment, the prescription is outside the scope of practice of the prescriber; or if the pharmacist has sufficient reason to question the validity of the prescription; or to protect the health and welfare of the patient.

(b) 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 in the absence of a current valid prescription, if, in his or her professional judgment, refusal would endanger the health or welfare of the patient.

1. The pharmacist must first ascertain to the best of his or her ability, by direct communication with the patient, that such a medication or device was prescribed for that patient by order of a licensed practitioner.

2. The pharmacist shall document the communication and require the patient to provide suitable identification and sign a statement attesting to the need before dispensing.

3. A patient's signature is not required for emergency refilling of a previously valid prescription.

13:39-6.2 Prescription prepared, compounded or dispensed by pharmacy externs or interns

A pharmacy intern or extern may prepare, compound or dispense prescriptions only under the direct supervision of a registered pharmacist of this State.

13:39-6.3 Identification tag

Each licensee shall wear an identification tag which shall include at least the pharmacist's first name, the first initial of his or her last name, and the designation "Pharmacist."

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).

13:39-6.4 Direct supervision of dispensing and compounding

The registered pharmacist supervising the activities of supportive personnel shall be physically present in the compounding/dispensing area and shall be personally responsible for the accuracy of the filled prescription.

13:39-6.5 Restriction on display of prescription legend drugs and controlled dangerous substances

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

13:39-6.6 Foreign prescriptions

Only those prescriptions written or signed by an authorized prescriber licensed to write prescriptions in the United States, District of Columbia, or any territory of the United States shall be considered valid prescription orders.

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

13:39-6.7 Supportive personnel

(a) Supportive personnel may assist the registered pharmacist in a clerical manner such as the retrieving of prescription files, profile cards, and other such records, the typing of labels and the completing of prescription receipts and other such forms.

(b) Supportive personnel shall not interpret a prescription order or consult with a patient or prescriber or the agent of the prescriber. Supportive personnel may, however, count, weigh, measure, or pour prescription medication under the direct supervision of the registered pharmacist as long as the contents and finished-product are verified by a registered pharmacist.

(c) There shall be no more than two supportive personnel, not including cashier, stocking and clerical help, being supervised by one pharmacist at any given time. Those personnel who do computer processing of prescriptions are to be included in the 2 to 1 ratio.

(d) Supportive personnel shall wear an identification tag, which shall include at least their first name, the first initial of their last name, and title.

(e) On yearly pharmacy permit renewal applications, the pharmacy shall list the name and address of all supportive personnel which it currently employs.

(f) When supportive personnel are engaged in any activity permitted by (b) above, the supervising registered pharmacist shall be responsible for all the activities of the supportive personnel.

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.

13:39-6.8 Advertising and sale of prescription drugs

(a) "Advertisement" means any attempt directly or indirectly by publication, dissemination, or circulation in print or electronic media which directly or indirectly induces or attempts to induce any person or entity to purchase or enter into an agreement to purchase services or goods from a Board licensee.

(b) Price quotations for prescription drugs appearing in any advertisement shall stipulate the strength and quantity required to be purchased for the offered cost. Price quotations shall include the usual and customary prescription cost. All services including, but not limited to, delivery charges rendered by the pharmacy which will add additional costs to the price quoted, must be set forth in the advertisement.

(c) Any reference in any form of advertisement to the quality of a drug or its beneficial use is prohibited.

(d) Price quotations for drugs appearing in any advertisement shall stipulate the effective period of price quotation.

(e) Upon request by any consumer, the pharmacist shall be required to give price information over the telephone and shall stipulate the effective period of the price quotation.

(f) All advertisements shall be predominantly informational and shall not be misleading, confusing or false. Any advertisement demeaning the quality of professional services rendered by another licensee or permittee shall be prohibited. No advertisement shall rely in any way on techniques to obtain attention that demonstrate a clear and intentional lack of relevance to the selection of professional services.

Case Notes

Prohibition against certain premiums or rebates was unconstitutional. *Matter of CVS Pharmacy, Wayne*, 224 N.J.Super. 631, 541 A.2d 242 (A.D.1988) reversed 116 N.J. 490, 561 A.2d 1160, certiorari denied 110 S.Ct. 841, 493 U.S. 1045, 107 L.Ed.2d 836.

13:39-6.9 Restriction on sale of Schedule V over-the-counter controlled substances

(a) It shall be considered unprofessional conduct for a pharmacist to dispense a Schedule V over-the-counter controlled substance when:

1. The pharmacist, in his or her professional judgment, knows or reasonably should know that the requested substance will be used for unauthorized or illicit consumption or distribution; or

2. The pharmacist, in his or her professional judgment, knows or reasonably should know that the person

requesting the substance previously used it for unauthorized or illicit consumption or distribution.

(b) The standard of professional judgment and care that attends the sale of a Schedule V over-the-counter controlled substance shall conform to the following:

1. All pharmacists shall comply with N.J.A.C. 8:65-7.19, which requires that the sale of specified controlled substances be limited in quantity during any 48-hour period, that the purchaser be at least 18 years of age, and that the pharmacist obtain suitable identification (including proof of age where appropriate) from every purchaser not known to the pharmacist.

2. In all instances, any doubts regarding the propriety of a sale of a Schedule V substance shall be resolved against making the sale.

3. The pharmacist shall enter every sale of a Schedule V substance in the Over-the-Counter Schedule V Record Book pursuant to N.J.A.C. 8:65-7.19. The information to be recorded shall include the purchaser's first and last name, street address, city and state, the name and quantity of the Schedule V substance sold, the date of each sale, and the name or initials of the pharmacist making the sale.

4. Upon an individual's second request for a Schedule V substance within a short period of time (two to four days), the pharmacist shall determine, through direct communication with the purchaser, whether the substance is being used correctly. In that regard, the pharmacist shall ascertain how many people are using the substance and whether the condition which the substance is being used to treat is improving.

5. Upon an individual's third request for a Schedule V substance within a short period of time relative to the number of persons using it (two to four days subsequent to the second purchase), the pharmacist shall advise the purchaser of the substance's abuse potential and shall caution the purchaser to consult a physician if the condition for which the substance is being used does not improve.

6. Upon an individual's fourth request for a Schedule V substance within a short period of time (two to four days subsequent to the third purchase), the pharmacist shall determine, through direct communication with the purchaser, how many people are using the substance, whether continued use will be therapeutic, whether the purchaser is treating a condition which requires a physician's consultation, whether the purchaser is exhibiting signs of drug abuse and whether the purchaser is making similar requests of other local pharmacies.

7. If a pharmacist determines that an individual's request for a Schedule V substance within a short period of time (two to four days) subsequent to his or her fourth purchase is warranted, the pharmacist shall document in the Over-the-Counter Schedule V Record Book the justification for such sale. In addition, the pharmacist shall recommend that the purchaser consult with a physician for medical evaluation due to the substance's abuse potential as well as the potential hazard presented by the substance's continued use.

8. If any Schedule V substance is dispensed to one individual more than five times within any 12-month period, the pharmacist shall obtain oral or written confirmation from the purchaser's physician as to the continued need for the substance and shall document such confirmation in the Over-the-Counter Schedule V Record Book.

New Rule, R.1990 d.478, effective October 1, 1990.
See: 22 N.J.R. 1329(a), 22 N.J.R. 3153(b).

SUBCHAPTER 7. PHARMACY FACILITY AND RECORDS

13:39-7.1 Retail pharmacy access and egress

Retail pharmacies shall be required to maintain entrances which are easily and safely accessible to the general public. Access to and egress from the pharmacy shall not be such that the public must traverse or traffic through any enterprise in which prescriptions are generated.

13:39-7.2 Retail pharmacy signs

Retail pharmacies shall be required to post a sign on the exterior of the building or a sign which is otherwise visible from a public roadway, conspicuously identifying the existence of a pharmacy on the premises, unless prohibited by lease agreement. In such case, a copy of the lease must be furnished to the Board.

13:39-7.3 Spatial requirement of a retail pharmacy prescription area

(a) For pharmacies in operation prior to July 1, 1963, the space devoted to the prescription area and laboratory shall not be less than 10 percent of the main floor area of the pharmacy or drugstore, and in no instance shall it be less than 50 square feet. If the main floor area of such pharmacy exceeds 1,200 square feet, the 10 percent requirement does not apply and the minimum requirement for the prescription area shall not be less than 120 square feet.

(b) For all other retail pharmacies including pharmacies subject to the provisions of (a) above which are moving to a new location, the prescription area must occupy exclusively a minimum of 150 square feet.

13:39-7.4 Prescription counter

There shall be a prescription counter or counters on which to work, and the free working space shall not be less than 18 inches in width and not less than 12 total feet in length. This minimum working surface shall be kept clear at all times for the compounding of prescriptions and other pharmaceutical manufacturing.

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

Inserted "or counters" following "counter", and substituted "total" for "continuous" following "12".

13:39-7.5 Prescription area sink

An adequate sink with hot and cold running water shall be provided in the prescription area of retail and institutional pharmacies, easily accessible to the prescription counter. A similarly equipped sink shall be easily accessible to institutional satellite pharmacies as well as institutional and retail pharmacy intravenous admixture anterooms.

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

Substituted a reference to anterooms for a reference to rooms.

13:39-7.6 Storage and adequate stock

There shall be sufficient shelf, drawer or cabinet space within the prescription area for proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, an adequate stock of prescription drugs and chemicals and the required equipment.

13:39-7.7 Minimum equipment and facilities

(a) The following minimum amount of equipment and facilities shall be required to be in every prescription area, and this equipment shall be stored so as to be readily accessible and shall be kept in a clean condition:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable current reference texts encompassing the general practice of pharmacy, drug interactions, drug product composition and patient counseling. Unabridged computerized versions of these reference texts shall be acceptable;
2. Over the counter Schedule V Record Book, if Schedule V medication is sold without a prescription;
3. Permanent prescription filing device and patient profile record system;
4. Properly safeguarded storage place for Schedule II controlled substances if not dispersed;
5. Class A prescription balance or equivalent electronic weighing device;
6. Set of metric weights;
7. Devices capable of measuring 0.3 ml to 500 ml;
8. A glass mortar and pestle;

9. Glass funnels;
10. Stirring rods;
11. A steel spatula and a spatula of rubber or composition;
12. Ointment tile or parchment paper;
13. Refrigerator, as required by United States Pharmacopoeia Standards, to be used only for the storage of pharmaceuticals;
14. Suitable counting trays or approved counting device;
15. Labels;
16. Auxiliary labels, including poison labels;
17. Suppository mold; and
18. Two Drug Utilization Review Council Placards and the current Drug Utilization Review Council Formulary.

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.196 effective June 21, 1999.

See: 30 N.J.R. 4113(a), 31 N.J.R. 253(a), 31 N.J.R. 1618(a).

In (a), added a reference to equivalent electronic weighing devices at the end of 5, and rewrote 15.

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), rewrote 1, 2 and 13.

Cross References

Reference materials, sterile admixture service, see also N.J.A.C. 13:39-11.16.

13:39-7.8 Cleanliness, orderliness and sanitation

The entire prescription area shall at all times be kept in a clean, orderly and sanitary condition.

13:39-7.9 Television in prescription area prohibited

No commercial television, other than for security measures, pharmacy training or patient counseling, may be operated in a prescription area or in any location outside of a prescription area such that its operation may be viewed from the prescription area.

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

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

Inserted references to pharmacy training and patient counseling.

13:39-7.10 Return of prescription medication

(a) No prescription medication shall be placed in stock for reuse or resale which has been returned after dispensing to a patient, except as provided in N.J.A.C. 13:39-9.15(a)2.

(b) Notwithstanding the provisions of (a) above, prescription medication incorrectly dispensed to a patient shall be accepted for return by the pharmacist and shall not be placed back in stock for reuse or resale.

Amended by R.1998 d.167, effective April 6, 1998.

See: 29 N.J.R. 4740(b), 30 N.J.R. 1298(a).

Amended N.J.A.C. reference.

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

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

Rewrote the section.

13:39-7.11 Prescription balances, scales, weights and automatic counting devices

All pharmacies shall prove to the satisfaction of the Board that all balances, scales, weights and automatic counting devices have been annually inspected by the Department of Weights and Measures of the municipality or county in which such pharmacy, drugstore, or other Board-licensed establishment is located, and that such balances, scales, weights and automatic counting devices have been properly sealed by the applicable authority.

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

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

13:39-7.12 Disposal of unwanted drugs

Unwanted drugs shall be disposed of in a manner that does not cause them to become a health hazard, and in accordance with all local, State, and Federal codes.

13:39-7.13 Outdated drugs or drugs marked "sample"

No outdated, misbranded, deteriorated or adulterated drugs, or any drugs marked "sample" or with any like designation or meaning shall be placed or maintained in active stock for use or sale.

13:39-7.14 Patient profile record system

(a) A patient profile system must be maintained by all pharmacies for persons for whom prescriptions are dispensed. The Patient Profile Record System (PPRS) shall be devised so as to enable the immediate retrieval of information necessary to enable the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing. One profile record may be maintained for members of a family living at the same address and possessing the same family name.

(b) The following information shall be recorded in the PPRS:

1. The family name and the first name of the person for whom the medication is intended (the patient);
2. The address and telephone number of the patient;
3. Indication of the patient's age, birth date or age group (infant, child, adult) and gender;
4. The original or refill date the medication is dispensed and the initials of the dispensing pharmacist, if said initials and such date are not recorded on the back of the original prescription or in any other Board-approved record;

5. The number or designation identifying the prescription;
6. The prescriber's name;
7. The name, strength and quantity of the drug dispensed; and
8. Pharmacist's comments relevant to the patient's drug therapy, including any failure of the patient to accept the pharmacist's offer to counsel.

(c) The pharmacist shall attempt to ascertain and shall record any allergies and idiosyncrasies of the patient and any medical conditions which may relate to drug utilization, as communicated to the pharmacist by the patient.

1. If there are no patient allergies, idiosyncrasies or medical conditions which may relate to drug utilization, the pharmacist shall so indicate on the patient profile record system.

(d) The pharmacist shall use professional judgment to review and monitor the patient profile, determine if there should be any adjustment in the original patient information and so indicate the appropriate change in the patient profile record.

(e) Upon receipt of a new or refill prescription, a pharmacist shall examine the patient's profile record either in a manual or electronic data processing system before dispensing the medication, to determine the possibility of a potentially significant drug interaction, reaction or misutilization of the prescription. Upon determining a potentially significant drug interaction, reaction or misutilization, the pharmacist shall take the appropriate action to avoid or minimize the problem, which shall, if necessary, include consultation with the patient and/or the prescriber.

1. Except as set forth in (e)5 below, before dispensing a new prescription, the pharmacist shall make reasonable efforts to counsel the patient or caregiver. Counseling may, but need not, include the following:

- i. The name and description of the medication;
- ii. The dosage form, dosage, route of administration, and duration of drug therapy;
- iii. Special directions and precautions for preparation, administration and use by the patient;
- iv. Common adverse or severe side effects or interactions and contraindications that may be encountered, including their avoidance, and the action required if they occur;
- v. Techniques for self-monitoring drug therapy;
- vi. Proper storage;
- vii. Prescription refill information; and
- viii. Action to be taken in the event of a missed dose.

2. The offer to counsel may be made by ancillary personnel. However, counseling may be performed only by the pharmacist.

3. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

4. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the prescription. A written offer to counsel shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.

5. The requirements to counsel the patient or caregiver upon receipt of a new prescription, as set forth in (e)1 through 4 above, shall not apply to a pharmacist who dispenses any drug to an inpatient at a hospital or a long term care facility in which the resident is provided with 24 hour nursing care.

6. Upon receipt of a refill prescription, a pharmacist shall determine if a substantial time, as is appropriate for that drug in the reasonable and prudent pharmacist's professional judgment, has elapsed from the last filling. When necessary, the pharmacist shall consult with the prescriber and/or the patient to assure himself or herself that continued use is appropriate.

7. When patient profile records indicate sporadic, erratic or irrational use of medication by a patient, the pharmacist shall consult with the patient and/or the prescriber to determine if continued use is appropriate.

8. All prescription patients who patronize a pharmacy shall have a profile record as specified by this section, and the pharmacist shall inquire as to whether other prescription drugs are being concomitantly utilized in order to establish a current drug history for the patient.

9. All of the foregoing assumes the patient is willing and capable of participating in his or her own plan of care.

(f) A patient profile record must be maintained for a period of not less than five years from the date of the last entry in the profile record. The oldest four years of record information shall be maintained in such a manner so as to be sight-readable within two weeks. The most recent one year of a record information must be immediately retrievable.

(g) If the pharmacy uses an electronic data processing system, an auxiliary recordkeeping system shall be established when the electronic data processing system is inoperative for any reason. When the electronic data processing system is restored to operation, the patient profile information and number of refills authorized during the time the

electronic system was inoperative shall be entered into the electronic data processing system within 72 hours.

(h) If an electronic data processing system is used, the system shall provide adequate safeguards against manipulation and alteration of records and to protect confidentiality of the information contained in the data bank.

(i) The holder of the pharmacy permit shall make arrangements with the supplier of data processing services or materials to ensure that the pharmacy will continue to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason.

(j) Failure to comply with this section shall subject the pharmacist to disciplinary sanctions.

Amended by R.1993 d.307, effective June 21, 1993.
See: 24 N.J.R. 266(a), 25 N.J.R. 2697(a).
Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

SUBCHAPTER 8. PHARMACY TRAINING SITES

13:39-8.1 Definitions

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

“Certified preceptor” means a pharmacist registered in this State who assumes the responsibility to supervise and tutor a pharmacy intern or extern as outlined in N.J.A.C. 13:39-8.2.

“Faculty preceptor” means a member of the faculty at an American Council of Pharmaceutical Education approved school or college of pharmacy, at which a pharmacy extern is enrolled, who assumes the responsibility to supervise and tutor a pharmacy extern as outlined in N.J.A.C. 13:39-8.2.

“Pharmacy intern” means any person who has graduated from an American Council of Pharmaceutical Education approved school or college of pharmacy, or if a foreign pharmacy graduate, any person who has satisfied the requirements of N.J.A.C. 13:39-3.11, who is employed in an approved training pharmacy for the purpose of acquiring accredited practical experience and who has first registered for said purposes with the Board.

“Pharmacy extern” means any person who is in the fifth or sixth college year (or third or fourth professional year) at an American Council of Pharmaceutical Education approved school or college of pharmacy who is assigned to a training site for the purpose of acquiring accredited practical experience under the supervision of the school or college at which he or she is enrolled.

“Pharmacy internship or externship” shall mean the program of acquiring practical experience by a pharmacy intern or extern respectively.

“Pharmacy training site” means a site which satisfies the requirements of N.J.A.C. 13:39-8.3.

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).

Deleted “Approved training site”; inserted “Faculty preceptor”; rewrote “Pharmacy intern” and “Pharmacy extern”; and added “Pharmacy training site”.

13:39-8.2 Preceptor certification application; procedures; responsibilities

(a) A registered pharmacist who wishes to be a certified preceptor shall apply to the Board and shall furnish evidence that he or she:

1. Has been registered and employed as a pharmacist in the area of practice in which he or she is to be engaged as a preceptor, on a full-time basis for at least two years in the State of New Jersey; and
2. Has a record of law observance.

(b) The Board shall approve a certified preceptor selected by each pharmacy intern, prior to the beginning of the internship. At no time may one certified preceptor supervise the training of more than one pharmacy intern.

(c) The certified preceptor in a pharmacy training site or a faculty preceptor shall report to the Board upon request on the progress and aptitude of any pharmacy intern or extern under his or her supervision.

(d) The compounding and dispensing of all prescriptions and drugs by the pharmacy intern or extern must be done under the direct supervision of a registered pharmacist.

(e) The certified preceptor or faculty preceptor is charged with the responsibility for the following:

1. Supervising the activities of the pharmacy intern or extern and ensuring that the intern or extern will keep abreast of developments in pharmacy by reading current professional literature and journals and by attending seminars and meetings of professional and scientific organizations; and
2. Providing the pharmacy intern or extern with experience and knowledge related to the preceptor’s area of practice.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Rewrote the section.

13:39-8.3 Pharmacy training site requirements

(a) To serve as a training site for interns, a pharmacy shall meet the following requirements:

1. Have a satisfactory record of observance of Federal, state and municipal laws and ordinances governing the activity in which it is or has been engaged.
2. Have a total number of prescriptions or medication orders filled annually, including renewals, of at least 20,000, with no more than one pharmacy intern or extern in training for each 20,000 prescriptions filled in the pharmacy.
3. Establish and maintain as part of the service it renders, a medication recordkeeping system for its patients that is approved by the Board.
4. Have available a reference library for use by the pharmacy intern.

(b) Notwithstanding the provisions of (a) above, a pharmacy which does not dispense medications but which serves as a pharmacy training site shall not be required to satisfy the requirements of (a)2 and 3 above.

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), rewrote the introductory paragraph and 4; and added (b).

13:39-8.4 Internship and externship practical experience

(a) The minimum accredited internship and externship practical experience requirement shall be the equivalent of 1,000 hours as follows:

1. One thousand hours for completion of a structured internship conducted after graduation from an accredited college of pharmacy and consisting of no less than 24 weeks supervised by a certified preceptor. Each week of practical experience shall consist of no less than 20 hours and no more than 45 hours of actual service per week. If the intern is a foreign pharmacy graduate, he or she must have met all of the requirements of the National Association of Board of Pharmacy Foreign Pharmacy Graduate Examination Commission.
2. The certified preceptor and the pharmacy intern shall keep accurate records of the time spent by the pharmacy intern for credit toward the requirements of (a)1 above. The Board shall provide appropriate forms to be submitted to the Board for approval of postgraduate practical experience.

3. No credit shall be given for hours served as an intern prior to the Board's receipt of the written application.

(b) In lieu of the requirements set forth in (a)1 above, an applicant may obtain up to 1,000 hours practical experience by completion of a structured, college-credited externship and clinical pharmacy clerkship program of an accredited

college of pharmacy. Such programs shall first be approved by the Board.

(c) In cases of a structured, college-credited externship and clinical pharmacy clerkship program, where less than 1,000 hours are accepted and approved by the Board, the balance of hours to make a total of 1,000 shall be gained through completion of a structured internship, conducted after graduation from an accredited college of pharmacy and supervised by a certified preceptor with each week of practical experience consisting of no less than 20 hours and no more than 45 hours of actual service per week.

(d) A Board-approved college of pharmacy externship program shall provide that no less than 75 percent of the hours credited toward the practical experience requirement of the Board be gained in settings in which there is direct involvement with consumers or patients, registered pharmacists, and other licensed health care practitioners such as physicians, dentists and nurses under the supervision of a certified or faculty preceptor. Not more than 45 hours of Board-accredited experience shall be acquired per week.

(e) Credit for college externships or other experience programs shall not be allowed for experience gained prior to the fifth college year (or third professional year) in the college of pharmacy program.

(f) The pharmacy college shall certify that the requirements of (b) above have been met. The Board shall provide appropriate forms for such certification.

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.1998 d.167, effective April 6, 1998.
See: 29 N.J.R. 4740(b), 30 N.J.R. 1298(a).

In (d), deleted language regarding practical experience hours in an approved training pharmacy.

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)2, substituted a reference to certified preceptors for a reference to preceptors; in (c), substituted "20 hours" for "35 hours" following "less than"; and in (d), inserted a reference to faculty preceptors in the first sentence, and substituted "40 hours" for "45 hours" in the last sentence.

13:39-8.5 Change in intern status

(a) A pharmacy intern applying for registration as a pharmacist in the State of New Jersey shall notify the Board within 10 days of any change in:

1. Beginning of a term of internship;
2. Termination of an internship;
3. Number of hours of employment;
4. Scheduled hours of employment;
5. Certified preceptor; and/or
6. Employing 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 (a)5, substituted a reference to certified preceptors for a reference to preceptors.

13:39-8.6 Committee on Pharmacy Internship and Externship

(a) A Committee on Pharmacy Internship and Externship shall be established which shall consist of:

1. Two members of the Board of Pharmacy;
2. Two faculty members of the College of Pharmacy of Rutgers, the State University of New Jersey;
3. Two fifth or sixth year pharmacy students from the College of Pharmacy of Rutgers, the State University of New Jersey; and
4. Four approved pharmacy certified preceptors, one of whom shall be a practicing pharmacist in an independent pharmacy, one of whom shall be a practicing pharmacist in a chain pharmacy, one of whom shall be a practicing pharmacist in an institution, and one of whom shall be a registered pharmacist whose primary employment is in the pharmaceutical manufacturing industry.

(b) The Committee is established to advise and assist the Board in all matters relating to the pharmacy internship/externship program.

(c) The President of the Board shall designate a member of the Board to be the chairperson of the Committee.

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)4, substituted a reference to certified preceptors for a reference to preceptors; deleted a former (c); and recodified former (d) as (c), and deleted a former first sentence.

13:39-8.7 Pharmacist intern log

(a) Pharmacist interns shall maintain a log for the internship period which meets the following requirements:

1. The log shall consist of an 8 by 11 inch looseleaf notebook.
2. Entries shall be made in the log weekly and shall contain:
 - i. The total number of prescriptions or medication orders filled in the pharmacy and the number filled by the intern;
 - ii. A brief summary of all new prescription drug products (new generic entities only) dispensed, such as physical-chemical characteristics, dosage, forms, and usage;
 - iii. Three examples of each of the following professional responsibilities:
 - (1) The use of the patient profile record requiring contact with patient, prescriber or hospital to resolve potential problems;

(2) Consultation with the patient or prescriber concerning special instructions regarding the use of medications;

(3) In a retail setting, consultation with the patient concerning over the counter medication;

iv. The certified preceptor's report;

v. Any atypical prescriptions compounded;

vi. Any change in status of any over the counter product;

vii. Any revision or addition in any Federal law or regulation or in New Jersey law or regulation concerning the practice of pharmacy;

viii. Any products or particular compounds removed from the market; and

ix. Any changes in product formulation.

(b) The log shall be submitted to the Board at the completion of the internship 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.1998 d.167, effective April 6, 1998.

See: 29 N.J.R. 4740(b), 30 N.J.R. 1298(a).

In (a)2iii, substituted "Three examples" for "One example".

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)2, inserted a reference to medication orders in i, substituted a reference to certified preceptors for a reference to preceptors in iv, and added v through ix.

SUBCHAPTER 9. PHARMACEUTICAL SERVICES WITHIN HEALTH CARE FACILITIES

13:39-9.1 Definitions

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

"Drug administration" means a procedure in which a prescribed drug is given to a patient by an authorized person in accordance with all laws and rules governing such procedures.

"Formulary" means a continually revised compilation of pharmaceuticals available in the pharmacy for use in the facility developed by the Pharmacy and Therapeutics Committee.

"Health care facility" means a place where patients and/or residents are cared for under a common roof such as hospitals, long term care facilities, and establishments similar to those delineated in N.J.S.A. 45:14-32.

“Health care system” means one or more health care facilities which are owned or controlled by the same legal entity.

“Institutional pharmacy” means the area in a health care facility or a health care system licensed by the Board as a pharmacy that maintains an institutional permit. “Institutional pharmacy” includes any areas of the health care facility or the health care system where pharmaceuticals are stored, compounded or dispensed.

“Medication order” means a written request for medication originated by an authorized prescriber and intended for patient use in the health care facility, and not for use of the institution’s employees or their dependents or outpatients of the facility’s clinics. A valid medication order contains the date ordered, the patient’s name and location within the facility, the name, dose, route, and frequency of administration of the medication, and any additional instructions. Computer-generated medication orders within an institutional setting, utilizing the prescriber’s electronic signature or password will meet legal requirements for a prescriber’s original handwritten signature on medication orders. Computerized signatures or passwords will be accepted provided that the facility has adequate safeguards which assure the confidentiality of each electronic signature or password and which prohibit their improper or unauthorized use.

“Pharmacy and Therapeutics Committee” means the active standing committee of the institution or health care facility which is the organizational line of communication and liaison between the medical and pharmacy staff and which acts to review and promote rational drug therapy and utilization in the facility. Its organization and function are described under N.J.A.C. 13:39-9.20.

“Unit dose drug distribution system” means a system of dispensing drugs to be administered to patients of the facility whereby the medications are delivered daily (or more frequently) by the pharmacy to the patient care units in amounts equal to a 24-hour supply or less and are prepared, whenever possible, in single unit use packaging.

“Unit use packaging” means a single unit use medication provided in sealed packaging which contains the following information for each dose:

1. Product name;
2. Strength;
3. Lot number;
4. Beyond use date; and
5. Manufacturer or repackager.

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.1998 d.167, effective April 6, 1998.
See: 29 N.J.R. 4740(b), 30 N.J.R. 1298(a).

Amended N.J.A.C. reference in “Pharmacy and Therapeutics Committee” definition.

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

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

Deleted “Authorized prescriber” and “Direct supervision”; in “Health care facility”, substituted a reference to patients and residents for a reference to the sick and injured; in “Unit dose drug distribution system”, deleted a reference to biologicals; and added “Unit use packaging”.

Amended by R.2000 d.457, effective November 20, 2000.

See: 31 N.J.R. 3044(a), 32 N.J.R. 4123(a).

Inserted “Health care system”; in “Institutional pharmacy”, inserted references to health care systems throughout, substituted “any” for “other” following “includes”, and deleted “manufactured,” following “stored.”.

13:39-9.2 Licensure of institutional pharmacies

(a) Any institutional pharmacy as defined under N.J.A.C. 13:39-9.1 shall be registered with and possess an institutional permit issued by the Board. The permit shall be conspicuously displayed in the facility’s pharmacy. The institutional pharmacy is subject to and shall be conducted in accordance with all existing State and Federal rules and regulations.

(b) An institutional pharmacy that is part of a health care system may fill medication orders for health care facilities that are part of the health care system and that provide pharmaceutical services directly to the patients of the health care system.

Amended by R.2000 d.457, effective November 20, 2000.

See: 31 N.J.R. 3044(a), 32 N.J.R. 4123(a).

Designated existing section as (a); and added (b).

13:39-9.3 Control of institutional pharmaceutical services

(a) The pharmaceutical services of the health care facility shall be the responsibility of and under the control, supervision, and direction of the registered pharmacist-in-charge.

(b) If a health care facility does not have an institutional pharmacy on its premises or chooses to utilize the services of a pharmacy outside the institution, it may enter into an agreement with a pharmacy licensed by the Board. The registered pharmacist-in-charge of that pharmacy and the designated pharmacist of the institution, if appropriate, shall direct, control, supervise and be responsible for the pharmaceutical services provided to the facility.

(c) The registered pharmacist-in-charge, with the cooperation of the Pharmacy and Therapeutics Committee, shall develop written policies and procedures as needed to provide pharmaceutical services to the facility. The written policies and procedures shall be available to the Board.

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).

Substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge throughout.

13:39-9.4 Pharmaceutical services

The pharmaceutical services shall be provided in accordance with accepted professional principles and standards and appropriate Federal, State and local laws. These services shall be responsive to the medication needs of the patient.

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

13:39-9.5 Pharmaceuticals

(a) The pharmacist-in-charge shall be responsible for determining the specifications for drugs and pharmaceutical preparations used in the treatment of patients of the facility as to quality, quantity and source of supply. An authorized purchasing agent and/or materials manager and/or pharmacy buyer of the facility may perform the actual procurement. In such a case, the purchase shall be approved by the pharmacist-in-charge or his or her designee, who shall be a pharmacist.

(b) Drugs approved by the Pharmacy and Therapeutics Committee for use in the facility shall be of an amount sufficient to compound or dispense all medication orders and prescriptions which may reasonably be expected to be compounded or dispensed by the pharmacist.

(c) The institutional pharmacy shall have an adequate inventory of drugs and biologicals to assure timely initiation of routine, emergency and disaster drug therapy;

(d) 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 these drugs shall not be construed to be a violation of N.J.A.C. 13:39-5.4. A facility participating in experimental research involving residents must be in compliance with Federal Department of Health and Human Services regulations, 45 C.F.R. Part 46, Protection of Human Subjects of Research.

(e) The pharmacist-in-charge shall establish a system of control for all drugs dispensed for use in the drug therapy of patients of the facility. Inspections shall be conducted of all medication areas located in the facility or any other service of the facility. These inspections shall be fully documented. Written inspection reports shall be prepared and signed by the inspecting pharmacist or by supportive personnel and co-signed by the supervising pharmacist. The pharmacist-in-charge shall be responsible for ensuring that, prior to performing any inspections pursuant to this subsection, supportive personnel are trained and can successfully demonstrate competency. Procedures for the review of these reports shall be developed and instituted by the pharmacist-in-charge and can be incorporated into the overall quality assurance program of the hospital.

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.196 effective June 21, 1999.
See: 30 N.J.R. 4113(a), 31 N.J.R. 253(a), 31 N.J.R. 1618(a).

In (e), deleted "by a pharmacist" following "conducted" in the second sentence, added "or by supportive personnel and co-signed by the supervising pharmacist" at the end of the fourth sentence, and inserted a new fifth sentence.

13:39-9.6 Drug disbursement; written orders; outpatient prescriptions

(a) The pharmacist shall review the prescriber's original order, a direct copy thereof, or an electro-mechanical facsimile before any initial dose of medication is dispensed, except as provided for in N.J.A.C. 13:39-9.9.

(b) Drugs not specifically limited as to time or number of doses when ordered shall be controlled by the automatic stop order procedure or other methods in accordance with written policies of the facility.

(c) Orders involving abbreviations and chemical symbols shall be carried out only if the abbreviations and symbols are included on a standard list that has been approved by the medical staff.

(d) When appropriate, the pharmacist shall make necessary entries into the patient medical record relative to drug use after consultation with the prescriber.

(e) Prescriptions written for employees of the institution or their dependents, or for outpatients of the facility's clinic, shall conform to the prescription requirements of N.J.S.A. 45:14-14.

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

Case Notes

Violation not found due to failure of Board to prove pharmacist's knowledge or receipt of equipment and test requirements. *New Jersey State Bd. of Pharmacy v. Yanuzzi*, 4 N.J.A.R. 489 (1981).

13:39-9.7 Drug disbursement; oral orders

(a) The mandatory requirements of this section shall be implemented in accordance with the policy and protocols of the Pharmacy and Therapeutics Committee.

(b) A pharmacist shall receive oral orders only from an authorized prescriber. Such orders shall be immediately recorded and signed by the person receiving the order on the prescriber's order sheet or into the electronic data processing system.

(c) Oral orders for Schedule II controlled substances shall be permitted only in the case of a bona fide emergency situation.

(d) Oral orders shall be countersigned by the prescriber.

(e) The pharmacist may release to the patient at discharge any remaining medication in a multiple dose container (for example, inhalers, multiple dose injectable medications such as insulin, topical preparation, drops, ointments, and topical irrigation solutions), provided that the pharmacist:

1. Labels the medication for out-patient use pursuant to labelling requirements set forth in N.J.S.A. 45:14-24;
2. Counsels the patient prior to discharge from the hospital or medical facility pursuant to N.J.A.C. 13:39-7.14; and

3. Ensures that discharge orders contain the attending physician's authorizations to release the remaining doses of the prescription to the patient or guardian.

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.1997 d.502, effective December 1, 1997.

See: 28 N.J.R. 5048(a), 29 N.J.R. 5072(a).

Inserted new (a); recodified existing (a) through (c) as (b) through (d); and added (e).

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

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

In (d), deleted "as required by 42 CFR 463" at the end.

13:39-9.8 Compounding

(a) Compounding of individual medication orders or prescriptions, the formulation of special drug needs and all bulk compounding (sterile or non-sterile) shall be done by or under the direct supervision of a pharmacist.

(b) Aseptic control procedures shall be maintained for the preparation of intravenous admixtures, the reconstitution of other sterile parenteral preparations, and the compounding and sterilization of other pharmaceutical products as needed.

(c) All prepackaging and labeling of drugs shall be done by or under the direct supervision of a pharmacist. Procedures shall be established for maintaining the integrity and manufacturer's control identity of prepackaged material. The prepackaging records shall be initialed by the supervising pharmacist.

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).

13:39-9.9 Monitoring of patient drug therapy

(a) The pharmacist shall be responsible for monitoring drug therapy of patients in the facility. This shall include, but is not limited to, maintaining and reviewing the patient medication profile prior to the dispensing of medications.

(b) In instances involving the issuance and administration of STAT orders (orders requiring immediate attention) these drugs shall be documented on the patient's medication profile immediately after dispensing.

(c) When the pharmacy is closed, these drugs shall be documented on the patient's medication profile immediately after the pharmacy is reopened.

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).

13:39-9.10 Medication not dispensed in finished form

The pharmacist shall be responsible for providing medication in a form that requires little or no further alterations, preparation, reconstitution, dilution or labeling by other licensed personnel. The pharmacist shall provide adequate instructions for those products that are not dispensed in finished form.

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).

13:39-9.11 Drug labeling

Labeling of medications, other than intravenous solutions, shall be in conformance with written policies and procedures controlling the drug distribution system in use within the facility and in accord with current acceptable standards of pharmaceutical practice. Dispensing and labeling of outpatient prescriptions shall conform to N.J.S.A. 45:14-14.

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).

Deleted a former (a); and deleted a former (b) designation.

13:39-9.12 Use of patient's own medication

(a) No drugs shall be administered to a patient except those provided through the pharmacy and except as provided by written policies and procedures developed by the registered pharmacist-in-charge and approved by the Pharmacy and Therapeutics Committee.

(b) Although the use of patient's own medications may be warranted in certain situations, it should be discouraged as a general or routine practice. If a patient's previously acquired medication is to be used, a written order to this effect shall be signed and dated by the patient's physician. Such medications shall be identified by the pharmacist as to contents and dispensing origin. Also, these medications shall be documented as part of the pharmacy's patient profile record system.

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 "and except as provided" for ". Any exception to this rule must be governed" following "pharmacy", and substituted a reference to registered pharmacists-in-charge for a reference to pharmacists-in-charge.

Case Notes

Violation found due to having outdated medication and "Not to be Sold" sample medications in prescription area; penalties (also cited as N.J.A.C. 13:39-9.2). *New Jersey State Bd. of Pharmacy v. Yanuzzi*, 4 N.J.A.R. 489 (1981).

13:39-9.13 Investigational drugs; removal of outdated and recalled drugs; emergency drug supply; controlled dangerous substances

(a) Investigational drugs shall be properly labeled and stored in the pharmacy until dispensed. Essential information on the investigational drug shall be maintained in the pharmacy. The investigational drug may be administered only after basic chemical, pharmaceutical and pharmacological information has been made available to all concerned and all the requirements of the Food and Drug Administration and the facility are satisfied.

(b) Procedures shall be established to assure the immediate and efficient removal of all outdated and recalled drugs from patient care areas and from the active stock of the pharmacy. The registered pharmacist-in-charge shall develop written policies and procedures governing the removal from the facility of outdated or recalled drugs.

(c) Limited quantities of emergency drugs shall be placed under controlled conditions in locations within the facility to assure immediate access by authorized licensed health care personnel for use in an emergency situation. Written policies and procedures for the maintenance, content, control and accountability of emergency drugs supplied and located throughout the facility shall be developed by the registered pharmacist-in-charge and approved by the Pharmacy and Therapeutics Committee.

(d) Controlled dangerous substances shall be purchased, received, stored, dispensed, administered, recorded and controlled in accordance with State and Federal laws and regulations. Written policies and procedures concerning control, use and accountability of controlled drugs shall be developed by the registered pharmacist-in-charge.

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 (b) through (d), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge.

Case Notes

Grand jury subpoena duces tecum reasonable; documents requested include patient profiles listing medication dispensed, as required under rule, to check against Medicaid claims submitted. In re Grand Jury Subpoena Duces Tecum, 143 N.J.Super. 526, 363 A.2d 936 (Law Div.1976).

Violations found for failure to maintain profile records on medication recipients (N.J.A.C. 13:39-9.13(a)); profile records kept did not reflect age group or category of recipients (N.J.A.C. 13:39-9.13(b)3); and records did not reflect allergies, idiosyncrasies and chronic conditions (N.J.A.C. 13:39-9.13(c)). New Jersey State Bd. of Pharmacy v. Yanuzzi, 4 N.J.A.R. 489 (1981).

13:39-9.14 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 registered 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 registered 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 in the facility, shall be performed under the direct 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 direct supervision of a pharmacist.

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

(e) Controlled substances and other medications to which, in the professional judgment of the registered 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 professional, every 24 hours. Other than a pharmacist, only authorized registered nurses, licensed *practical* nurses, physicians, authorized prescribers or designated pharmacy supportive personnel 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 prescriber. 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 licensed 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 registered 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.

(h) The pharmacist shall be responsible for checking the drugs in the drug-dispensing devices at least monthly for expiration date, misbranding, physical integrity, security and accountability.

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.

13:39-9.15 Disposal of unused medications

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

1. All medications where the drug source, control number or expiration 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 cosigned and witnessed by a licensed nurse, physician or pharmacist and disposed of by the health care facility according to its written protocol.

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.

13:39-9.16 Records and reports

(a) Records of the pharmaceutical services of the facility shall be the responsibility of the registered pharmacist-in-charge. These records shall be maintained and made available to persons authorized to inspect them under State and Federal statutes and regulations.

(b) The institutional pharmacy shall maintain a patient profile record for each patient receiving drug therapy in accordance with N.J.A.C. 13:39-7.14 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 initials of the pharmacist performing the dispensing or supervising; the reported diagnosis allergies and chronic condition(s) of the patient.

2. All notations made on the inpatients' profile records by supportive personnel shall be verified and countersigned by the supervising pharmacist.

3. The inpatient profile record shall be filed and stored in a readily retrievable manner for five years following patient discharge.

(c) All outpatient prescriptions dispensed and outpatient profile records in the institutional pharmacy shall be signed or initialed by the dispensing pharmacist, dated, filed and kept for not less than five years from the last dispensing record date.

(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 registered 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.

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.

13:39-9.17 Drug information and education

(a) The registered 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. 13:39-7.7.

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

1. A copy of the current institutional formulary;
2. A reference drug compendium which will give basic information concerning drugs approved by the Pharmacy and Therapeutics Committee; and
3. The telephone number of either the local or regional poison control center.

(c) The pharmacist shall participate in the drug education programs of the facility.

Recodified from 13:39-9.8 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; and in (b), deleted a former 1, a recodified former 2 through 4 as 1 through 3.

13:39-9.18 After hours access to the institutional pharmacy

(a) Only a pharmacist shall have access to the pharmacy stock of controlled dangerous substances in Schedules II through V.

(b) Only a pharmacist shall have access to the institutional pharmacy except that in a pharmacist's absence from an institution, a registered nurse designated by the registered pharmacist-in-charge may obtain medication from the hospital pharmacy as needed in an emergency and not available as floor stock.

(c) A designated registered nurse shall remove only those medication doses which shall be administered prior to the opening of the pharmacy. The designated registered nurse may remove the following from the pharmacy stock of drugs or automated dispensing device:

1. A drug in its original container or a drug pre-packaged by the pharmacy for use in the institution;
2. The required dose(s) of a drug from the original container for a specific patient.

(d) The registered pharmacist in charge shall obtain from the registered nurse on a suitable form a record of any drugs removed showing the following:

1. The name of the drug;
2. The dosage size;
3. The amount taken;
4. The date;
5. The patient's name and location; and
6. The signature of the nurse.

(e) The registered pharmacist in charge shall obtain with the record in (d) above the container from which the required dose(s) was taken for drug administration purposes in order that it may be properly checked by a pharmacist.

(f) All records in (d) above shall be kept by the pharmacy for one year.

Recodified from 13:39-9.9 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 (b) and (c); in (d) and (e), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge; and in (e), substituted a reference to required doses for a reference to single doses.

13:39-9.19 Advisory committees

The registered pharmacist-in-charge, or designee, shall be an actively participating member on any committees of the facility that may be concerned with drugs and their utilization.

Recodified from 13:39-9.10 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).

Substituted a reference to registered pharmacist-in-charge for a reference to pharmacist-in-charge.

13:39-9.20 Pharmacy and Therapeutics Committee

In all health care facilities providing pharmaceutical services to patients, an active standing committee of the institution entitled the Pharmacy and Therapeutics Committee or other appropriate name shall be established. A Pharmacy and Therapeutics Committee shall be multidisciplinary and include a pharmacist.

Recodified from 13:39-9.11 by R.1994 d.351, effective July 18, 1994.

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

13:39-9.21 Institutional pharmacy staff

The institutional pharmacy shall be staffed by sufficient, competent personnel in keeping with the size, scope and complexity of the pharmaceutical services provided.

Recodified from 13:39-9.12 by R.1994 d.351, effective July 18, 1994.

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

13:39-9.22 Pharmacist staff

(a) The institutional pharmacist staff shall include the following:

1. A registered pharmacist-in-charge, who shall direct the institutional pharmacy service and be responsible to the administration of the facility;
2. Pharmacists who shall assist the registered pharmacist-in-charge as required depending on the size, scope and complexity of the service;
3. Any pharmacy interns, externs, and students, who shall function in accordance with the Board's rules and under certified preceptor(s) or faculty preceptor(s); and
4. Supportive and clerical personnel who shall work under the direct supervision and control of a registered pharmacist as provided in N.J.A.C. 13:39-6.4 and 6.7.

Recodified from 13:39-9.13 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 references to registered pharmacists-in-charge for references to pharmacists-in-charge in 1 and 2, substituted a reference to certified preceptors for a reference to qualified preceptors and inserted a reference to faculty preceptors in 3, and added 4.

13:39-9.23 (Reserved)

Recodified from 13:39-9.14 by R.1994 d.351, effective July 18, 1994.

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

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

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

Section was "Supportive personnel staffing".

13:39-9.24 Pharmacy facilities; space

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

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

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

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

13:39-9.25 Storage and security

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

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

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

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

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

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

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

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

13:39-9.26 Equipment

Adequate equipment shall be provided for the compounding, packaging, labeling, refrigeration, sterilization, testing and safe distribution of drugs and other functions. The

equipment shall be sufficient to process drugs required by the facility.

Recodified from 13:39-9.17 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Deleted a reference to biologicals.

13:39-9.27 Institutional decentralized pharmacies

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

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

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

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

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

2. Patient profile record system;

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

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

5. Labels; and

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

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

SUBCHAPTER 10. AUTOMATED MEDICATION SYSTEMS**Authority**

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

Source and Effective Date

R.2000 d.28, effective January 18, 2000.
 See: 31 N.J.R. 2293(b), 32 N.J.R. 317(a).

13:39-10.1 Purpose and scope

The rules in this subchapter establish standards applicable to all pharmacies and/or facilities that utilize automated medication systems to store, package, dispense and distribute prescriptions or medication orders.

13:39-10.2 "Automated medication system" definition

As used in this subchapter, "Automated medication system" means any process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing and distribution of medications, and which collects, controls and maintains all transaction information. "Automated medication system" does not mean an automatic counting device operated pursuant to N.J.A.C. 13:39-7.11 or a mechanical drug dispensing device operated pursuant to N.J.A.C. 13:39-9.14.

13:39-10.3 Authority to use automated medication system

(a) A pharmacy may use an automated medication system to fill prescriptions or medication orders provided that:

1. The registered pharmacist in charge or the registered pharmacist under contract with a healthcare facility responsible for the dispensing of medications, pursuant to N.J.S.A. 45:14-32, if an automated medication system is utilized at a location which does not have a pharmacy on-site, is responsible for the supervision of the operation of the system;

2. The Board has conducted an inspection of the pharmacy, including an inspection of the automated medication system;

3. The automated medication system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the Board upon request; and

4. The pharmacy has made the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the system.

(b) The registered pharmacist in charge or the registered pharmacist under contract with a healthcare facility responsible for the dispensing of medications shall be responsible for the following:

1. Reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality and prevention of unauthorized access and malfunction;

2. Ensuring that medications in the automated medication system are inspected, at least monthly, for expiration date, misbranding and physical integrity, and ensuring that the automated medication system is inspected, at least monthly, for security and accountability;

3. Assigning, discontinuing or changing personnel access to the automated medication system;

4. Ensuring that the automated medication system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation; and

5. Ensuring compliance with all applicable provisions of N.J.A.C. 13:39.

13:39-10.4 Written policies and procedures of operation

(a) When an automated medication system is used to fill prescriptions or medication orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:

1. Include a table of contents;

2. Include a description of all procedures of operation;

3. Set forth methods that shall ensure retention of each amendment, addition, deletion or other change to the policies and procedures of operation for at least two years after the change is made. Each such change shall be signed or initialed by the registered pharmacist in charge and shall include the date on which the registered pharmacist in charge approved the change;

4. Set forth methods that shall ensure that a pharmacist currently licensed in the transmitting jurisdiction reviews and approves the transmission of each original or new prescription or medication order to the automated medication system before the transmission is made;

5. Set forth methods that shall ensure that access to the records of medications and other medical information of the patients maintained by the pharmacy is limited to licensed practitioners or personnel approved to have access to the records, for the purpose of complying with N.J.A.C. 13:39-7.14(h);

6. Set forth methods that shall ensure that access to the automated medication system for stocking and retrieval of medications is limited to licensed practitioners or qualified support personnel acting under the supervision of a registered pharmacist. An accountability record which documents all transactions relative to stocking and removing medications from the automated medication system shall be maintained; and

7. Identify the circumstances under which medications may be removed from the automated medication system by a licensed practitioner for distribution to a patient without prior order review by a registered pharmacist.

(b) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall, at least annually, review its written policies and procedures of operation and revise them if necessary.

(c) A copy of the written policies and procedures of operation adopted pursuant to this section shall be retained at the pharmacy and at the healthcare facility where the automated medication system is utilized. Upon request, the pharmacy shall provide to the Board a copy of the written policies and procedures of operation for inspection and review.

13:39-10.5 Personnel training requirements

The registered pharmacist in charge shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all licensed practitioners and supportive personnel are trained in the pharmacy's standard operating procedures with regard to automated medication systems as set forth in the written policies and procedures of operation maintained pursuant to N.J.A.C. 13:39-10.4.

13:39-10.6 Written program for quality assurance

(a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall operate according to a written program for quality assurance of the automated medication system which:

1. Requires continuous monitoring of the automated medication system;
2. Establishes mechanisms and procedures to test the accuracy of the automated medication system at least every six months and whenever any upgrade or change is made to the system;
3. Establishes a protocol for measuring the effectiveness of the automated medication system;
4. Requires the pharmacy to report to the Board each recurring error of the automated medication system. A "recurring error," for purposes of this section, means any specific type of inaccuracy within the automated medication system that occurs more than twice within a 14 day period; and
5. Requires the pharmacy to maintain all documentation relating to the written program for quality assurance for at least two years.

13:39-10.7 Written plan for recovery

(a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from a disaster which interrupts the ability of the pharmacy to provide services. The written plan for recovery shall include:

1. Planning and preparation for a disaster;
2. Procedures for response to a disaster;

3. Procedures for the maintenance and testing of the written plan for recovery; and

4. A procedure to notify the Board, each organization which has contracted with the pharmacy, each patient of the pharmacy, and other appropriate agencies, of a disaster and the date on which the pharmacy expects to recommence the provision of service.

13:39-10.8 Written program for preventative maintenance of automated medication system

A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system.

SUBCHAPTER 11. STERILE ADMIXTURE SERVICES IN RETAIL AND INSTITUTIONAL PHARMACIES

13:39-11.1 Purpose and scope

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

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

13:39-11.2 Definitions

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

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

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

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

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

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

"Controlled environment" means a designated area for sterile product preparation.

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

Former N.J.A.C. 13:39-11.2, Training requirements, was recodified to N.J.A.C. 13:39-11.7.

13:39-11.3 Sterile admixture services; environment

A sterile admixture service is one specializing in the compounding and dispensing of sterile products upon receipt of a valid prescription or medication order. Such compounding shall take place in the confines of a controlled environment as required by N.J.A.C. 13:39-11.17; or when circumstances permit as set forth in N.J.A.C. 13:39-11.12(c), in a laminar hood, as provided by N.J.A.C. 13:39-11.23, or in a glove box, as provided by N.J.A.C. 13:39-11.24.

Amended by R.1995 d.269, effective June 5, 1995.

See: 27 N.J.R. 43(a), 27 N.J.R. 2239(a).

New Rule, R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Former N.J.A.C. 13:39-11.3, Supportive personnel; required supervision, was recodified to N.J.A.C. 13:39-11.8.

13:39-11.4 Compliance

(a) A retail pharmacy which compounds and dispenses sterile admixture products as of June 15, 1998 or applies to compound and dispense sterile admixture products commencing after June 15, 1998 shall meet the requirements of this subchapter subject to the following exception:

1. A retail pharmacy which compounds and dispenses sterile admixture products as of June 15, 1998 shall meet the requirements of N.J.A.C. 13:39-11.17(b)4 and 11.18(g) by December 15, 1999. Individual pharmacies may request additional time by making application to the Board and demonstrating significant hardship or other good cause.

(b) An institutional pharmacy which compounds and dispenses sterile admixture products as of June 15, 1998 shall meet the requirements of this subchapter by December 15, 1999. Individual pharmacies may request additional time by making application to the Board and demonstrating significant hardship or other good cause.

(c) An institutional pharmacy which applies to the Board for an approval to compound and dispense sterile admixture products commencing after June 15, 1998 shall meet the requirements of this subchapter.

New Rule, R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Former N.J.A.C. 13:39-11.4, Tracking document, was recodified to N.J.A.C. 13:39-11.10.

13:39-11.5 General requirement

An applicant or permit holder who wishes to prepare sterile admixtures shall notify the Board at least 30 days prior to commencement of preparation of any sterile admixture products, and must receive approval from the Board before commencing sterile admixture preparation.

New Rule, R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Former N.J.A.C. 13:39-11.5, Information required to appear on prescription label, was recodified to N.J.A.C. 13:39-11.11.

13:39-11.6 Pharmacist in charge and permitholders' responsibilities

(a) That section of a pharmacy which provides a sterile admixture service shall be under the direct supervision of a pharmacist licensed to practice in this State.

(b) The pharmacist in charge shall have the responsibility, in that section of the pharmacy which provides this special service for, at a minimum, the following:

1. Preparation of sterile admixtures compounded within the pharmacy or pharmacy satellite;

2. Storage of all materials pertinent to the preparation of sterile admixtures, including drugs, chemicals and biologicals, and the establishment of specifications for procurement of the materials;

3. Labeling of all containers of sterile admixture preparations compounded with the pharmacy;

4. Recording all transactions of the pharmacy as may be applicable to State, Federal and local laws and rules, as may be necessary to maintain accurate control over, and accountability for, all pharmaceutical materials; and

5. Ensuring that only licensed pharmacists meeting the requirements of (a) above, or supportive personnel under direct supervision of an IV trained licensed pharmacist as defined in N.J.A.C. 13:39-11.8(a), prepare, compound and dispense the sterile admixture preparations.

New Rule, R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Former N.J.A.C. 13:39-11.6, Expiration date of sterile preparation, was recodified to N.J.A.C. 13:39-11.12.

13:39-11.7 Training requirements

(a) The pharmacist in charge and all personnel involved in sterile admixture preparation shall have practical or academic training in sterile product compounding, clean room technology, laminar flow technology, and quality assurance techniques. Such training shall be documented for each person before that individual begins to compound sterile products and annually thereafter. That documentation shall be maintained by the permit holder for five years and made available to the Board upon request.

(b) The pharmacist in charge shall be responsible for ensuring that, prior to performing delegated sterile admixture services, all supportive personnel are trained and can successfully demonstrate:

1. Comprehensive knowledge of the pharmacy's standard operating procedures with regard to sterile admixture services as set forth in the policy and procedure manual required to be maintained pursuant to N.J.A.C. 13:39-11.14;

2. Familiarity with the necessary compounding techniques; and

3. Appropriate aseptic technique, which shall be proven by means of a test batch of culture media, media fill or the equivalent.

(c) At least annually, the pharmacist in charge shall be responsible for testing the aseptic technique of all personnel involved in sterile product preparation by means of a test batch of culture media, media fill or the equivalent. Test results shall be maintained for five years, and shall be made available for the Board's inspection upon request. Individuals who fail to demonstrate acceptable aseptic technique shall be prohibited from engaging in sterile product preparation until demonstrating acceptable technique by means of a test batch of culture media, media fill or the equivalent.

Recodified from N.J.A.C. 13:39-11.2 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Rewrote the section. Former N.J.A.C. 13:39-11.7, Handling, packaging and delivery, was recodified to N.J.A.C. 13:39-11.13.

13:39-11.8 Supportive personnel; required supervision

(a) Dispensing pharmacists shall provide direct supervision to supportive personnel who are performing delegated sterile admixture tasks. The ratio of dispensing pharmacists to supportive personnel shall not exceed 1:2 at any given time.

1. For the purpose of this subchapter, "direct supervision" means that the dispensing pharmacist shall be present in the pharmacy dispensing area whenever supportive personnel are compounding sterile admixture products, and shall conduct checks of all steps in preparation, compounding and dispensing of sterile admixture products.

2. Supervision shall include, but is not limited to, the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

(b) The dispensing pharmacist may delegate to supportive personnel only the following tasks: recording of the prescription, selection of the drugs, container and diluent, typing of labels and compounding of the sterile admixture. The dispensing pharmacist shall ensure that each task has been performed correctly in the dispensing process.

Recodified from N.J.A.C. 13:39-11.3 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Rewrote the section. Former N.J.A.C. 13:39-11.8, Policy and procedure manual, was recodified to N.J.A.C. 13:39-11.14.

13:39-11.9 Batch preparation

Pharmacists and supportive personnel may prepare sterile products consistent with the provisions of N.J.A.C. 13:39-11.8 in a quantity that is supported by prior valid prescription orders before receiving a valid written prescription or medication order, provided the pharmacist can document a history of valid prescriptions subsequently received shortly thereafter or medication orders that have been generated solely within an established professional prescriber-patient-pharmacist relationship, and provided they maintain the prescription on file for all such products dispensed at the pharmacy as required by state law. The pharmacist shall document the batch preparation process in accordance with N.J.A.C. 13:39-11.10(e).

New Rule, R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Former N.J.A.C. 13:39-11.9, Quality assurance program, was recodified to N.J.A.C. 13:39-11.15.

13:39-11.10 Documentation

(a) Consistent with the provisions of N.J.A.C. 13:39-11.6, the dispensing pharmacist shall ensure that the sterile admixture product has been properly prepared, labeled, controlled, stored, dispensed and distributed in accordance with the provisions of this subchapter.

(b) The pharmacist in charge shall be responsible for ensuring that policies and procedures exist so that all aspects of the dispensing process set out in (e) below are documented and that the pharmacist responsible for each preparation can be identified.

(c) The retail dispensing pharmacist shall be responsible for completing a form which documents the completion of each of the steps of the compounding process in (e) below. The tracking document(s) shall be initialed by the individual(s) who completed each step.

(d) The institutional dispensing pharmacist shall assure that appropriate documentation is maintained to track completion of the steps of the compounding process set out in (e) below.

(e) Compounding steps which shall be documented are as follows:

1. Receipt of prescription;
2. Recording of prescription in the patient record profile system, pursuant to N.J.A.C. 13:39-11.16;
3. Correct selection of the drugs, container, and diluent prior to their being compounded;
4. Verification that all pharmacy sterile admixture compounding is performed within a class 100 laminar air flow hood or class 100 clean room and that proper aseptic procedures are being used at all times to prevent bacterial contamination of this product;
5. Verification that residual components comply with the prescription;
6. Verification that the prescription label complies with the requirements of N.J.A.C. 13:39-11.11; and
7. Verification that the prescription is complete and ready to be dispensed, including any necessary ancillary supplies.

(f) The completed documentation shall be maintained for not less than five years from the date of the last entry in the record. The oldest four years of record information shall be maintained in such a manner so as to be sight-readable within two weeks. The most recent one year of a record must be retrievable within 24 hours.

Recodified from N.J.A.C. 13:39-11.4 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Rewrote the section. Former N.J.A.C. 13:39-11.10, Patient profile records, was recodified to N.J.A.C. 13:39-11.16.

13:39-11.11 Information required to appear on prescription label

(a) The dispensed container for any sterile admixture product shall bear a permanently affixed label with at least the following information:

1. The date and time prepared;
2. In the retail pharmacy only, the name of the prescriber;
3. The name of the patient;
4. Directions for use;
5. The name of the base solution;
6. The name and quantity of drug(s) added;
7. The name or identifying code of the pharmacist who checked or prepared the sterile admixture product;
8. The name, address, and telephone number of the pharmacy;
9. The pharmacy's Drug Enforcement Administration (DEA) number, if the sterile admixture product contains any controlled dangerous substances;
10. The expiration date and time of the sterile admixture product (If no time is stated, it is presumed to be 11:59 P.M. of the stated expiration date);
11. Any ancillary and cautionary instructions as needed;
12. As pertinent, a warning consistent with applicable Federal and State law that cytotoxic products are biohazardous; and
13. As pertinent, the requirements for proper storage.

Recodified from N.J.A.C. 13:39-11.5 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

In (a), inserted a reference to time in 1, and rewrote 2 and 10. Former N.J.A.C. 13:39-11.11, Controlled environment: entry, was recodified to N.J.A.C. 13:39-11.17.

13:39-11.12 Expiration date of sterile preparation

(a) The expiration date of a sterile admixture product shall be 24 hours or as otherwise stated by the manufacturer or current literature at the time of preparation.

(b) Any expiration date that extends beyond 24 hours or the manufacturer's expiration date shall be substantiated by documentation satisfactory to the Board.

(c) In an institutional pharmacy, any sterile admixture product which is prepared under the pharmacy's control in a

class 100 laminar air flow hood which is in an environment which meets the requirements of N.J.A.C. 13:39-11.23, shall be labeled to indicate that administration to a patient shall be initiated and completed within 28 hours of the beginning of the preparation time. If such a product is prepared by closed-system aseptic transfer of a single, sterile, nonpyrogenic, finished medication obtained from licensed manufacturers into sterile final containers (for example, syringes, minibags, portable infusion-device cassettes), then the product shall be labeled to indicate that administration to a patient shall be completed within the time recommended by the manufacturer but not exceeding 30 days after preparation. A closed system aseptic transfer is one which does not permit exposure of the pharmaceutical components to the environment, and shall be prepared in a class 100 laminar air flow hood.

Recodified from N.J.A.C. 13:39-11.6 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

In (a), added "or current literature at the time of preparation" at the end of the sentence; and inserted a new (c). Former N.J.A.C. 13:39-11.12, Controlled environment: construction, was recodified to N.J.A.C. 13:39-11.18.

13:39-11.13 Handling, packaging and delivery

(a) The pharmacy shall be responsible for the proper handling and packaging of compounded sterile preparations for delivery from the pharmacy to the patient in order to assure and maintain sterility and stability of these preparations. To ensure the integrity and efficacy of compounded sterile admixture products, the pharmacist in charge shall ensure that:

1. A reasonable effort is made to provide tamper-evident packing;
2. Retail delivery is made from the pharmacy to the patient within a reasonable time; and
3. Proper in-transit storage is provided consistent with product labeling.

Recodified from N.J.A.C. 13:39-11.7 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

In (a), inserted a new first sentence in the introductory paragraph and changed "Delivery" to "Retail delivery" in 2. Former N.J.A.C. 13:39-11.13, Controlled environment: stocking, was recodified to N.J.A.C. 13:39-11.19.

13:39-11.14 Policy and procedure manual

(a) The pharmacist in charge shall maintain a policy and procedure manual which shall set forth in detail the licensee's standard operating procedures with regard to sterile admixture services.

(b) The policy and procedure manual shall include policies and procedures governing the following:

1. A risk-management program (including, but not limited to, incident report procedures, an adverse drug reaction system, and a product contamination system);

2. Security measures ensuring that the premises where sterile admixture drugs are present are secured, so as to prevent access by unauthorized personnel;

3. Equipment;

- i. Procedures for use; and
- ii. Documentation of appropriate certifications;

4. Sanitation standards and procedures;

5. Reference materials as set out in N.J.A.C. 13:39–7.7 and 11.25;

6. Information concerning drug:

- i. Preparation;
- ii. Storage and handling;
- iii. Dispensing;
- iv. Labeling;
- v. Delivery; and
- vi. Destruction, recalls and returns;

7. Patient recordkeeping as set forth in N.J.A.C. 13:39–11.16;

8. Handling, dispensing and documentation of investigational new drugs;

9. A quality assurance program as set forth in N.J.A.C. 13:39–11.15;

10. Verification of training and competency guidelines as set forth in N.J.A.C. 13:39–11.7;

11. Compounding process validation;

12. Documentation as set forth in N.J.A.C. 13:39–11.10;

13. Description of appropriate garb;

14. Conduct guidelines for personnel in the controlled areas;

15. Personnel responsibilities;

16. Patient education (retail patients);

17. Protocol and procedures to maintain the integrity of the interior work area of the laminar air flow hoods; and

18. Written procedures in compliance with the Occupational Safety and Health Administration standards for handling small and large spills of antineoplastic agents and other hazardous substances.

(c) The pharmacist in charge shall review and, if necessary, amend the policy and procedure manual on at least an annual basis. Documentation of the annual review shall be made available to the Board upon request.

Recodified from N.J.A.C. 13:39–11.8 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Rewrote (b). Former N.J.A.C. 13:39–11.14, Controlled environment: maintenance and supplies, was recodified to N.J.A.C. 13:39–11.19(c) through (e).

Amended by R.1999 d.196 effective June 21, 1999.

See: 30 N.J.R. 4113(a), 31 N.J.R. 253(a), 31 N.J.R. 1618(a).

In (b), added 18.

13:39–11.15 Quality assurance program

(a) This section shall apply both to commercially available sterile drug products that are dispensed to patients without compounding or other manipulation, and to sterile admixture products, which, prior to dispensing, have *been in* any way repackaged, reconstituted, diluted, admixed, blended, or otherwise manipulated (collectively referred to as “compounded”).

(b) The dispensing pharmacist shall ensure that the sterile admixture product retains its quality attributes within acceptable limits through a written quality assurance program. The quality assurance program shall require at least that:

1. A reasonable effort shall be made by the dispensing pharmacist to assure that sterile admixture products shall be kept under appropriate controlled conditions at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration as set forth by the product manufacturer, with each sterile admixture product dispensed;

2. The quality assurance program encompasses all phases of sterile admixture product preparation, distribution, storage, administration, and directions for use for each type of product dispensed;

3. All compounding processes representative of all types of manipulations, products and batches must be sterile tested and validated at least every 12 months.

4. Air and surface sampling for microbial organisms in class 100 laminar air flow hoods and class 1,000 clean rooms is done twice annually and at any time when microbial contamination is suspected pursuant to United States Pharmacopoeia/National Formulary guidelines;

5. Laminar air flow hoods shall be certified every six months by an independent certification company;

6. The class 1,000 clean room and class 10,000 ante-room shall be certified every six months by an independent certification company; and

7. All unused drugs and materials used in the preparation of sterile admixture products, including antineoplastic agents, are disposed of properly in accordance with accepted professional standards and applicable laws, including the Medical Waste Act (N.J.S.A. 13:1E–48.1 et seq., P.L. 1989, c.34).

Recodified from N.J.A.C. 13:39–11.9 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

In (a), substituted "sterile" for "injectable" following "available"; and rewrote (b). Former N.J.A.C. 13:39-11.15, Clean room, was recodified to N.J.A.C. 13:39-11.20.

13:39-11.16 Patient profile records

(a) The pharmacist in charge shall ensure that a patient profile record is maintained and monitored for each patient. The patient profile record shall include, but is not limited to, the following:

1. Available medical information consistent with N.J.A.C. 13:39-7.14; and
2. All medication orders for institutional patients.

(b) The pharmacist in charge shall ensure that a reasonable, documented attempt is made to include in the record over-the-counter and home remedies used by noninstitutional patients.

(c) The pharmacist in charge shall ensure that initial and ongoing multidisciplinary clinical monitoring and comprehensive care plans are maintained and readily available.

Recodified from N.J.A.C. 13:39-11.10 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Rewrote (a) and (b) and inserted a new (c). Former N.J.A.C. 13:39-11.16, Anteroom, was recodified to N.J.A.C. 13:39-11.21.

13:39-11.17 Controlled environment: use, access, location; temperature

(a) The pharmacy shall have a designated area for sterile product preparation, known as the "controlled environment," consisting of a clean room and an anteroom unless the pharmacy meets the requirements of N.J.A.C. 13:39-11.23 or 11.24.

(b) A controlled environment shall be:

1. Accessible only to designated personnel;
2. Used only for the preparation of sterile products, or such other tasks that require a controlled environment;
3. Structurally isolated from other areas within the pharmacy by means of restricted entry or access; and
4. Air conditioned to maintain a temperature of 59 to 77 degrees Fahrenheit.

Recodified from N.J.A.C. 13:39-11.11 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Rewrote (a); and in (b), substituted "sterile" for "parenteral" in 2 and added a new 4.

13:39-11.18 Controlled environment: construction

(a) The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the controlled environment shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby minimizing spaces in which microorganisms and other contaminants may accumulate.

(b) All surfaces shall be resistant to damage from sanitizing agents.

(c) Junctures where ceilings meet wall shall be covered, caulked or sealed to avoid cracks and crevices where dirt can accumulate.

(d) Ceilings which consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic and shall either be caulked or weighted and clipped.

(e) Solid walls shall consist either of panels locked together and sealed, or of epoxy-coated gypsum board.

(f) Floors shall have vinyl floor covering and shall be seamless or have heat-welded seams and coving to the sidewall.

(g) There shall be no dust-collection overhangs (such as ceiling utility pipes) or ledges (such as window sills). All sprinkler heads shall be flush with the ceiling.

(h) Ceiling lighting fixtures shall have exterior lens surfaces which are smooth, mounted flush, and air tight.

(i) All areas in ceilings and walls where the surface has been penetrated shall be sealed.

(j) Any clean room construction other than that specified in (a) through (i) above (for example, softwall, prefabricated, modular, portable clean rooms) shall be approved by the Board prior to installation and use.

Recodified from N.J.A.C. 13:39-11.12 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

In (b), inserted "damage from"; in (e), substituted "Solid walls" for "Walls"; rewrote (g) and (i); and added a new (j).

Amended by R.1999 d.196 effective June 21, 1999.

See: 30 N.J.R. 4113(a), 31 N.J.R. 253(a), 31 N.J.R. 1618(a).

In (d), substituted "either be caulked or weighted and clipped" for "also be caulked around each perimeter to seal them to the support frame" at the end.

13:39-11.19 Controlled environment: stocking, maintenance and supplies

(a) The controlled environment shall contain only the following:

1. Items such as furniture, equipment, supplies, and other goods which are required for the tasks to be performed there;
2. Items which are nonpermeable, nonshedding, and resistant to disinfectants; and
3. Items which have been cleaned and sanitized immediately prior to their being placed in the clean room.

(b) Whenever possible, equipment and other items used in the controlled environment should not be taken from

these rooms except for calibration, servicing, or other activity associated with the proper maintenance of the item.

(c) The controlled environment shall be kept clean and arranged in an orderly fashion. All required equipment shall be maintained in good operating condition.

(d) The controlled environment shall not be used for bulk storage, warehousing, or clerical and secretarial functions.

(e) The controlled environment area shall contain the following supplies:

1. Gloves, masks, gowns, and other personal protective equipment;
2. Needles and syringes of various sizes;
3. Disinfectant cleaning agents;
4. Clean towels;
5. Hand-washing materials, including antimicrobial skin cleaner; and
6. Any and all supplies necessary for the aseptic preparation of sterile admixture products.

Recodified from N.J.A.C. 13:39-11.13 and 13:39-11.14 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote (a)3.

13:39-11.20 Controlled environment: clean room

(a) The clean room shall contain no sinks or floor drains.

(b) Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that the work surfaces may be readily cleaned and sanitized.

(c) The clean room shall be a minimum of 100 square feet in size and shall be compatible with the volume of compounding being conducted.

(d) Appropriate environmental control devices capable of maintaining class 1,000 air-quality conditions during normal activity shall be in place.

(e) The clean room shall contain the following equipment:

1. A laminar airflow hood or suitable HEPA filter system;
2. Waste containers in compliance with Occupational Safety and Health Administration (OSHA) standards for used needles and syringes, and for chemotherapy waste; and
3. Ancillary supplies required for proper compounding.

Recodified from N.J.A.C. 13:39-11.15 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Rewrote (d); and in (e), deleted former 2 and recodified former 3 and 4 as 2 and 3.

13:39-11.21 Controlled environment: anteroom

(a) The anteroom shall have an air quality of Class 10,000 or better.

(b) The anteroom shall contain the following equipment:

1. A sink with hot and cold running water;
2. Waste containers for all personal protective equipment;
3. An eyewash station; and
4. A hazardous waste spill kit.

(c) A refrigerator, as required by United States Pharmacopoeia Standards, shall be reasonably accessible to the anteroom to ensure the integrity of the sterile admixture product, but shall not be located within the controlled environment.

Recodified from N.J.A.C. 13:39-11.16 and amended by R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

In (b), deleted former 2 and recodified former 3 through 5 as 2 through 4; and deleted (d).

13:39-11.22 Vertical air laminar flow hoods

(a) Pharmacies shall compound antineoplastic agents and other hazardous substances in a class 100 vertical air laminar flow hood.

(b) Personnel who compound and dispense antineoplastic agents and other hazardous substances shall adhere to OSHA Work Practice Guidelines, as set forth in CPL 2-2.20B CH-4, Chapter 21, incorporated herein by reference, as amended and supplemented.

New Rule, R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

13:39-11.23 Laminar air flow hoods not in a clean room

Institutional pharmacy class 100 laminar air flow hoods not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in sterile product preparation. Such hoods shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

New Rule, R.1998 d.297, effective June 15, 1998.

See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

13:39-11.24 Controlled environment: self-contained sterile glove boxes

Self-contained class 10 to class 100 glove boxes, barrier isolation technology or the equivalent not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in sterile product preparation. Such boxes shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

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

13:39-11.25 Library references

In addition to the minimum reference library mandated in N.J.A.C. 13:39-7.7, each sterile admixture service shall contain recognized references pertinent to specialized sterile admixture practice.

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

13:39-11.26 Disposal of drugs and materials

All unused drugs and materials used in the preparation of sterile admixture products, including antineoplastic agents, shall be disposed of properly in accordance with accepted professional standards and applicable laws, including the Medical Waste Act (N.J.S.A. 13:1E-48.1 et seq., P.L. 1989, c.34), so as not to endanger the public health.

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

13:39-11.27 Security

The sterile admixture area and its contents and other areas where sterile admixture drugs are present shall be secured, so as to prevent access by unauthorized personnel.

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

SUBCHAPTER 12. NUCLEAR PHARMACIES

Subchapter Historical Note

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).

13:39-12.1 Definitions

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

“Authentication of product history” includes, but is not limited to, identifying the purchase source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical.

“Authorized practitioner” means a practitioner duly authorized by applicable Federal and State law to possess, use and administer radiopharmaceuticals.

“Designated agent” means an individual under the direct supervision of a practitioner authorized to communicate the practitioner’s instructions to the nuclear pharmacy.

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

“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).

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 direct 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.

(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 direct 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.

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

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

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

1. The area for the storage, compounding and dispensing of radioactive drugs shall be completely separate from pharmacy areas for non-radioactive drugs;
2. Hot lab and storage area shall be a minimum of 120 square feet; and
3. The compounding and dispensing area shall be a minimum of 300 square feet.

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

1. Dose calibrator;
2. Refrigerator;
3. Drawing station;
4. Well scintillation counter;
5. Microscope;
6. Chromatographic apparatus or comparable means of effectively assuring tagging efficiency;

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

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

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

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

2. State statutes and rules relating to pharmacy;

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

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

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

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

In (c), rewrote the introductory paragraph and 1.

13:39-12.5 Quality control

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