CHAPTER 39

STATE BOARD OF PHARMACY

Authority

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

Source and Effective Date

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).

Executive Order No. 66(1978) Expiration Date

Chapter 39, State Board of Pharmacy, expires on June 16, 1999.

Chapter Historical Note

Chapter 39, State Board of Pharmacy, was filed and became effective prior to September 1, 1969. Chapter 39 was repealed and replaced with new rules by R.1989 d.314, effective June 19, 1989.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 was readopted as R.1994 d.351. 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.

"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 the statement, "Caution: Federal law prohibits dispensing without a prescription" or words of similar import; or

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

"Licensed practitioner" means a duly licensed physician, dentist, veterinarian or other health care practitioner.

"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 certificate is in good standing for the current registration 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).

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 National Association of Boards of Pharmacy Licensing Examination (NABPLEX).	
	(1) Law examination	60.00.
	iii. Reciprocal fee	125.00.
	iv. Reinstatement of licensure	225.00 plus application fee.
	v. Initial registration 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 registration	140.00.
	vii. Replacement registration certificate	25.00.
	viii. Transfer of grades	125.00.
	ix. Late renewal fee	100.00.
	x. Replacement wall certificate	40.00.
	xi. Continuing education review fee	10.00.
	xii. Continuing education program: provider review fee	50.00.
	xiii. Yearly fee for distribution of minutes and agenda	60.00.
2.	For pharmacies as follows:	
	i. Pharmacy permits	
	(1) Application for permit	275.00.
	(2) Annual renewal	175.00.
	(3) Change of ownership	275.00.
	(4) Change of location	275.00.
	ii. Replacement permit certificate	25.00.
	iii. Replacement wall permit	25.00.
	iv. Late renewal fee	100.00.

Amended by R.1993 d.414, effective August 16, 1993.
See: 25 N.J.R. 1666(a), 25 N.J.R. 3839(a).

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 Education requirements

(a) An applicant for the written examination 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 College 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).

13:39–2.2 Application to be filed

An applicant for the written examination must file an application for such examination at least 30 days prior to the date of the examination unless this requirement is waived by the Board because of extenuating circumstances. The required fees as prescribed in N.J.A.C. 13:39–1.3 must 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.

13:39–2.3 Birth certificate

An applicant for the written examination who was born in the United States shall submit the original or a certified copy of his or her birth certificate which will be retained by the Board. The birth certificate must bear the name under which the application for the examination is being made. In those instances where there has been a legal name change, documentation attesting to the legal name change must be submitted along with the birth certificate.

13:39–2.4 (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".

13:39–2.5 Language comprehension requirement

All applicants for licensure who earned their undergraduate pharmacy degree in countries wherein the primary language is other than English, prior to being granted licensure, shall comply with the requirements of N.J.A.C. 13:39–3.11.

13:39–2.6 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 written examination; however, the applicant shall not be eligible for licensure until attaining legal age.

13:39–2.7 Proof of character

(a) An applicant for the written examination shall submit, in advance, an application containing evidence of good moral character which is an on-going 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).

13:39–2.8 Proof of identity of applicant

An applicant for the written examination must submit to the Board 30 days in advance of the date of the written examination a bust 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.

13:39–2.9 Alleged violations of Pharmacy Act

If an applicant for any Board examination is involved in 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.

13:39–2.10 Written examinations; grades

(a) The written examination shall be that of the National Association of Boards of Pharmacy (NABPLEX). An applicant shall attain a passing grade of not less than 75. If an applicant fails the examination, he or she will be required to repeat the examination.

(b) The applicant shall also pass a written examination on the laws governing the practice of pharmacy in the State of New Jersey. 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.

(c) If the applicant should fail either the NABPLEX or the law examination three times, the applicant shall be required to take review courses as approved by the Board prior to retaking the failed examination(s).

SUBCHAPTER 3. REGISTRATION OF PHARMACISTS

13:39–3.1 Certificate of registration

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

13:39–3.2 Duplicate certificate of registration

A duplicate certificate of registration 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 certificate of registration or upon return of the damaged original certificate to the Board.

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 certificate is issued, the original certificate must be returned for cancellation along with the required fee as prescribed in N.J.A.C. 13:39–1.3.

13:39–3.4 Change of employment or address

A registered pharmacist shall notify the Board in writing of any change in his or her home address 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).

13:39–3.5 Certification of records

Upon payment of the required fee as prescribed in N.J.A.C. 13:39–1.3, a certification of any of the information on file in the Board records concerning an application for registration of a registered pharmacist will be supplied.

13:39–3.6 Reproduction of original certificate of registration prohibited

The original certificate of registration 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, without the express written authorization of the Board.

13:39–3.7 Limitation or reciprocal registration

(a) Reciprocal registration 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 the state of original licensure provide for an adequate evaluation of the applicant's education, training and experience.

13:39–3.8 Basic requirement for transfer of licensure

An application for reciprocal registration to the State of New Jersey shall fully meet all of the requirements in effect in this State as of the date of his or her registration in the state of original licensure, or in any other state of licensure by examination, including the District of Columbia and territories of the United States.

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

(a) An applicant for reciprocal registration to the State of New Jersey must 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, 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.

13:39–3.10 Clear record of law observance

Eligibility for reciprocal registration shall be denied any person against whom there are pending any formal charges for any alleged 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 must meet the character requirements outlined in N.J.A.C. 13:39–2.7.

13:39–3.11 Foreign graduates

(a) All pharmacist applicants with a degree from countries where the primary language is other than English, prior to being granted licensure as professional pharmacists in this State, shall submit to the Board evidence that they are certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy. In order to receive FPGEC certification, applicants must document their educational backgrounds, successfully complete the Test of English as a Foreign Language (TOEFL) Examination, the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) and have attained a minimum passing score in each examination. FPGEC certification shall have been obtained within two years of application for licensure in this State.

(b) A request for waiver of the FPGEC certificate must delineate good cause for the waiver request. The Board may, after due consideration and within its own discretion, waive the TOEFL examination component 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).

13:39–3.12 Physical and mental competence of reciprocal registrants

(a) An applicant for reciprocal registration 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).

13:39–3.13 Preliminary application

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

13:39–3.14 New Jersey pharmacy law examination: reciprocal registration

(a) The applicant for reciprocal registration shall pass a written test on the laws governing the practice of pharmacy in this State. 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 registration fails the examination three times, the applicant shall be required to take review courses as approved by the Board prior to retaking the law examination.

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 certificate of registration through the payment of a registration renewal fee as prescribed by N.J.A.C. 13:39–1.3 and the filing of a renewal application to be obtained from the Board.

(b) The renewal application shall list the name, home address, original certificate of registration number, places and hours of employment, continuing education credits, 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).

13:39–3.16 Duplicate renewal certificate of registration

If a renewal certificate of registration is lost or destroyed, a duplicate renewal certificate 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 certificate originally issued must be submitted.

13:39–3.17 Reinstatement in good standing

(a) If a registered pharmacist permits his or her registration to lapse for a period of less than five years through a failure to renew his or her certificate of registration, the registration may be brought into good standing through payment as per N.J.A.C. 13:39–1.3(a)1iii of the current and lapsed renewal fee and upon submission of proof of identity and the filing of an application to be obtained from the Board.

(b) If the registration has lapsed for a period of five years or longer, the applicant for such reinstatement must pass the New Jersey pharmacy law examination. Copies of excerpts of the laws governing the practice of pharmacy in the State of New Jersey will be supplied to the applicant by the Board beforehand for study purposes. The applicant shall also submit payment as per N.J.A.C. 13:39–1.3(a)1iii of the current renewal fee and proof of identity along with an application to be obtained from the Board.

(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.

13:39–3.18 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 pharmacist-in-charge of a pharmacy or other Board-licensed establishment, the incoming 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 pharmacist-in-charge of a pharmacy or other Board-licensed establishment, he or she shall so advise the Board in writing within 30 days by completing a form provided by the Board.

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

1. Employment and supervising personnel in a prescription department or pharmacy department;

2. Maintaining accurate records of all prescription medication received and dispensed;

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

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

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

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

7. Ensuring that all dispensed medication is properly labeled;

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

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

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

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

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

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

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

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

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 becomes null and void. If the operation of the pharmacy is to be continued, the estate or heirs of the deceased partner and 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.

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 not less than 30 days in advance of the change of ownership 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.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

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

(a) Whenever a pharmacy or licensed establishment changes location, the pharmacy or licensed establishment shall apply on a form prescribed and furnished by the Board at least 30 days in advance of the proposed date of opening at the new location. The pharmacy or licensed establishment shall pay a fee for the new permit pursuant to N.J.A.C. 13:39–1.3.

(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.

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 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) 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).

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. 13:39–5.8.

(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.

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 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 the pharmacist-in-charge shall be posted so as to be visible from outside of the department. The telephone number of the 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).

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 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.

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".

(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 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.

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 acceptable 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 review-

able 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

(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 at a retail pharmacy and 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 in-patient medication orders, as defined in N.J.A.C. 13:39–9.1, in an institutional pharmacy may accept all in-patient medication orders, including orders for Schedule II substances, which have been transmitted by technological device.

(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).

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 (Reserved)

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".

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.

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

13:39–6.8 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 on which to work, and the free working space shall not be less than 18 inches in width and not less than 12 continuous feet in length. This minimum working surface must be kept clear at all times for the compounding of prescriptions and other pharmaceutical manufacturing.

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 must be easily accessible to institutional satellite pharmacies as well as institutional and retail pharmacy intravenous admixture 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. The current USP DI and supplements and suitable current reference texts encompassing the general practice of pharmacy, drug interactions and drug product composition. Unabridged computerized versions of these reference texts shall be acceptable;
2. Over the counter Schedule V Record Book;
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;
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;
14. Suitable counting trays or approved counting device;
15. Labels, upon dispensing to contain the name of the registered pharmacist-in-charge, and the address and telephone number of the pharmacy;
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).

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, 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.

13:39–7.10 Return of prescription medication

No prescription medication shall be placed in stock for reuse or resale which has been returned after leaving the pharmacy, except as provided in N.J.A.C. 13:39–9.6(a)13ii.

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. INTERNSHIPS; EXTERNSHIPS; APPROVED 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.

"Approved training site" means a site approved by the Board to provide accredited practical experience to pharmacy interns or externs.

"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.

"Pharmacy intern" means any person who has graduated from an accredited school or college of pharmacy approved by the Board, or if a foreign pharmacy graduate, any person who has met all of the requirements of the National Association of Boards of Pharmacy Foreign Pharmacy Graduate Examination Commission in order to qualify to take the National Association of Boards of Pharmacy Licensing Examination (NABPLEX), 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 accredited school or college of pharmacy approved by the Board who is assigned to an approved 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.

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

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

(a) A registered pharmacist who wishes to be a certified preceptor shall make application to the Board upon such form as shall be prescribed and shall furnish evidence satisfactory to the Board that he or she:

1. Has been registered and employed as a pharmacist on a full-time basis for at least two years in the State of New Jersey;

2. Has been engaged in the compounding and dispensing of pharmaceutical preparations and prescriptions and the supplying of drug products in a registered pharmacy for a period of at least two years, one year of which must have been immediately prior to the beginning of any pharmacy internship he or she is to supervise;

3. Has a record of law observance deemed satisfactory by the Board; and

4. Has attended professional meetings or preceptor training conferences as may be designated by the Board.

(b) The Board shall assign a certified preceptor to each pharmacy intern. At no time may one certified preceptor supervise the training of more than one pharmacy intern. The Board reserves the right to determine the suitability of pharmacists to serve as preceptors.

(c) The certified preceptor in an approved training pharmacy must indicate a willingness to cooperate with the Board in developing pharmacy intern or extern training and shall report to the Board from time to time as requested by the Board 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 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;

2. Providing the pharmacy intern or extern with experiences that will make the intern or extern proficient in compounding and dispensing of pharmaceutical preparations, drug products, health aids and related items;

3. Providing the pharmacy intern or extern with instruction and guidance in:

i. Procedure for opening and closing a pharmacy;

ii. General pharmacy operation;

iii. Ordering drugs and checking drug orders;

iv. Over the counter preparation, including their composition and consultation with consumers;

v. Drug Enforcement Administration inventory and preparation of Drug Enforcement Administration orders;

vi. Sale of Drug Enforcement Administration Schedule V preparations and sale of poisons;

vii. Third-party prescriptions programs;

viii. Telephone procedure with prescribers and patients;

ix. Consulting with prescribers and patients; and

x. Usage of reference books in the pharmacy and reference material from other sources;

4. Arranging an interview with a physician or other authorized prescriber for the intern or extern; and

5. Preparing the intern or extern in any other area of pharmacy important to good management and professional practice.

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

13:39–8.3 Training pharmacy approval

(a) To be approved as a training pharmacy for interns and externs, 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 an adequate reference library for use by the pharmacy intern or extern.

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

13:39–8.4 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 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 must 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 35 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. No less than 50 percent of the hours credited toward the practical experience requirement of the Board shall be acquired in an approved training pharmacy under the supervision of a certified preceptor. Not more than 40 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).

13:39–8.5 Change in intern status

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. 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).

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 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) All meetings of the Committee shall be held in accordance with the Open Public Meetings Act, N.J.S.A. 10:4–6 et seq.

(d) All members of the Committee shall be approved by the Board. The President of the Board shall designate a member of the Board to be the chairperson of the Committee.

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 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. One example 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; and

iv. The preceptor's report.

(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).

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:

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

"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 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.

"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 the sick and injured 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.

"Institutional pharmacy" means the area in the health care facility licensed by the Board as a pharmacy that maintains an institutional permit. This area shall include, but is not limited to, other areas of the health care facility where pharmaceuticals are stored, manufactured, compounded and 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. 13:39–9.11.

"Unit dose drug distribution system" means a system of dispensing drugs and biologicals 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.

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

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

13:39–9.2 Licensure of institutional pharmacies

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.

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 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 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 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).

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 by a pharmacist 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. 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).

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) 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.

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

(c) Oral orders shall be countersigned by the prescriber as required by 42 CFR 463.

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).

13:39–9.8 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) Asceptic 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).

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

(a) Whenever drugs are added to intravenous solutions, supplementary labeling shall be affixed to the container indicating the names and amounts of all ingredients, the name and location of the patient, the date and time of expiration and the initials of the supervising or dispensing pharmacist.

(b) 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).

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. Any exception to this rule must be governed by written policies and procedures developed by the 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).

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) There shall be procedures 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 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 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 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).

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, idiosyncracies 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 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 drug-dispensing device shall be checked for accuracy and cleanliness every 24 hours by a pharmacist when on duty and so documented.

1. 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.

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

3. At least every 24 hours, a pharmacist shall check medications withdrawn from the drug-dispensing device. Other than a pharmacist, only authorized registered nurse(s) shall have access to the withdrawal of medication from each drug-dispensing device during authorized times of use. A record of all withdrawals, including the identity of the registered nurse making the withdrawal, shall be recorded and available to the pharmacist.

4. A pharmacist shall check the record of all medications withdrawn from the drug-dispensing device against the order as written by the authorized prescriber. This check shall be performed and documented within 24 hours from the time of the original order and so noted on the pharmacy's patient medication profile.

5. 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 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.

6. 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).

13:39–9.15 Disposal of unused medications

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

1. All medications where the drug source, control number or expiration date are missing, shall be sent to the pharmacy for final disposition as required.

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 non-administered controlled dangerous substances expended or wasted either by accident or intent shall be signed and witnessed by a licensed nurse, physician or pharmacist and returned to the pharmacy with a written explanation.

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).

13:39–9.16 Records and reports

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

(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 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. This information shall be made available to the Food and Drug Administration or other appropriate agencies upon request.

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).

13:39–9.17 Drug information and education

(a) The pharmacist-in-charge shall be responsible for maintaining drug standards, references and sources of drug information current and adequate to meet the needs of the pharmacists, physicians, nurses, other health care personnel, and patients of the facility. Reference texts shall include, but not be limited to, those required by the Board under N.J.A.C. 13:39–7.7.

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

1. A metric-apothecary conversion table;

2. A copy of the current institutional formulary;

3. A reference drug compendium which will give basic information concerning drugs approved by the Pharmacy and Therapeutics Committee; and

4. 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).

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 pharmacy stock of drugs except that in a pharmacist's absence from an institution, a registered nurse designated by the institution may obtain medication from the hospital pharmacy's stock of drugs as needed in an emergency and not available as floor stock. Only one registered professional nurse in any given shift shall have access to the pharmacy stock of drugs.

(c) The pharmacist-in-charge may designate a registered nurse to remove the following from the pharmacy stock of drugs:

1. A drug in its original container or a drug prepackaged by the pharmacy for use in the institution;

2. A single dose of a drug from the original container for a specific patient.

(d) The 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 pharmacist in charge shall obtain with the record in (d) above the container from which the single dose 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).

13:39–9.19 Advisory committees

The 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).

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 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 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 qualified preceptor(s).

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).

13:39–9.23 Supportive personnel staffing

Supportive personnel in the institutional pharmacy 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 13:39–9.14 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–9.24 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 and biologicals 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 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).

13:39–9.26 Equipment

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

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. The current USP DI and supplements and suitable reference texts;

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).

SUBCHAPTER 10. STERILE ADMIXTURE SERVICES IN RETAIL AND INSTITUTIONAL PHARMACIES

13:39–10.1 Sterile admixture services defined

A sterile admixture service is one involving the dispensing and specializing in the compounding and distribution of sterile parenteral products.

13:39–10.2 Compliance

(a) An institutional pharmacy which compounds and dispenses sterile admixture medications, parenteral nutrition and/or parenteral drug therapy shall meet the requirements of this subchapter.

(b) A retail pharmacy which, on or prior to September 19, 1994, compounded and dispensed sterile admixture medications, parenteral nutrition and/or parenteral drug therapy shall meet the requirements of this subchapter.

(c) A retail pharmacy which, on or prior to September 19, 1994 compounds and dispenses sterile admixture medications, parenteral nutrition and/or parenteral drug therapy shall meet the requirements of N.J.A.C. 13:39–11.

Amended by R.1994 d.476, effective September 19, 1994.
See: 26 N.J.R. 1303(a), 26 N.J.R. 3878(b).

13:39–10.3 General requirement

A pharmacy presently supplying or intending to supply a sterile admixture service shall notify the Board.

13:39–10.4 Pharmacist's 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 who should have practical or academic training in sterile product compounding, clean room technology, laminar flow technology, and quality assurance techniques. The registered pharmacist should have an adequate pharmacy background in clinical application of intravenous drug therapy either through experience or academic training.

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

1. Preparation of sterile admixtures compounded within the pharmacy;

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;

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. Assuring that only licensed pharmacists meeting the requirements of (a) above or supportive personnel under direct supervision of a pharmacist prepare, compound, and dispense the sterile admixture preparations.

13:39–10.5 Handling, packaging and delivery

(a) The pharmacy shall provide special handling and packaging of compounded parenteral preparations for delivery from the pharmacy to the patient in order to assure and maintain sterility and stability of these preparations. The dispensed container shall bear a permanently affixed label with at least the following information:

1. Date prepared;

2. Name of physician, except for institutional inpatients;

3. Name of the patient;

4. Directions for use;

5. Name and amount of drug(s) added;

6. Name of the basic solution;

7. Name or identifying code of the pharmacist who checked or prepared the admixture;

8. The expiration date of the sterile preparation, which shall be the manufacturer's recommended expiration date or 24 hours, unless otherwise stated by the manufacturer, or an extended time may be substantiated with adequate documentation. This date shall appear on the label;

9. Name, address and telephone number of the pharmacy, except for institutional inpatients; and

10. Any ancillary and cautionary instructions as needed.

(b) Delivery of compounded parenteral preparations from the pharmacy to the patient shall be made within a reasonable time in order to ensure integrity and efficacy.

13:39–10.6 Patient records

A patient profile record shall be maintained and monitored for each patient. The patient profile record must contain available medical information consistent with prevailing pharmacy standards, and the complete record of the formulations of the sterile products which were dispensed.

13:39–10.7 Policy and procedure manual

(a) A policy and procedure manual shall be maintained at each pharmacy and be available for inspection by authorized agents of the Board. The policy and procedure manual shall set forth, in detail, the objectives and operational guidelines of the permit holder. The policy and procedure manual shall be maintained in current status. The Manual shall contain written documentation of such objectives and operational guidelines, including:

1. Microbiological evaluation, consistent with current standards for preparation of total parenteral nutrition, antineoplastic agents, antibiotics, large and small volume parenterals or other parenteral therapy;

2. Security;

3. Equipment;

4. Sanitation;

5. Reference materials;

6. Drug storage;

7. Drug dispensing;

8. Drug labeling;

9. Drug destruction and returns;

10. Delivery of drugs;

11. Recordkeeping;

12. Investigational new drugs; and

13. A quality assurance program which monitors personnel qualifications, training, performance, equipment, facilities, and such others as may be specified by the Board.

13:39–10.8 Pharmacy environment

(a) The compounding and dispensing of sterile admixture preparations shall be conducted in a pharmacy environment subject to the pharmacy permit laws of this State and in accordance with those requirements for the safe handling of drugs.

(b) The environment for this practice shall be set apart and designed and equipped to provide controlled aseptic conditions. Aseptic technique shall prevail in this environment to minimize the possibility of microbial contamination.

13:39–10.9 Minimum requirements for space

(a) The area for preparing sterile admixtures as provided for in these rules shall be referred to as the sterile admixture area and shall be set apart from general work and storage areas. This area shall be adequately air conditioned to maintain a temperature of 59 to 86 degrees Fahrenheit. This separated area is to be used solely for the aseptic compounding of sterile admixture products.

(b) The sterile admixture area shall provide space for a minimum of one laminar air flow hood. The area shall be of adequate size to accommodate other equipment as provided in these rules and sufficient space to allow the pharmacist and other personnel in the sterile admixture area to adequately, safely, and accurately fulfill their duties related to sterile compounding.

(c) For the compounding and dispensing of antineoplastic agents, there shall be sufficient additional space to accommodate a vertical air laminar flow hood.

(d) The sterile admixture area shall have adequate space necessary for the storage, compounding, labeling, dispensing, and sterile preparation of drugs, and additional space as needed, depending on the size and scope of pharmaceutical services.

(e) The sterile admixture area shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

13:39–10.10 Minimum requirements for equipment

(a) The sterile admixture area shall contain the following equipment:

1. A suitable laminar air flow hood;

2. A sink with hot and cold running water exclusive of restroom facilities, shall be easily accessible to the personnel preparing sterile admixtures. This sink shall be maintained in a sanitary condition at all times.

3. A refrigerator as required by U.S.P. standards exclusively for storing of IV admixtures shall be easily accessible to personnel preparing the sterile admixtures; and

4. Appropriate waste containers for:

i. Used needles and syringes; and

ii. All waste including disposal of apparel used in preparation of antineoplastics.

13:39–10.11 Supplies

(a) The sterile admixture area shall maintain the following supplies:

1. Gloves, masks, and gowns;

2. Needles and syringes of various sizes;

3. Disinfectant cleaning agents;

4. Clean towels;

5. Handwashing materials, including antimicrobial skin cleaner; and

6. Any and all supplies necessary for the aseptic preparation of sterile admixture products.

13:39–10.12 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 references pertinent to this specialized practice.

13:39–10.13 Compounding requirements

(a) All sterile admixture compounding shall be performed within a certified air flow environment. Laminar air flow hoods or environments shall be certified and so documented at least semiannually.

(b) Proper aseptic procedures must be used at all times to prevent bacterial contamination of the product.

13:39–10.14 Disposal of drugs and materials

All unused drugs and materials used in the preparation of sterile admixture solutions, including antineoplastic agents, must be disposed of properly in accordance with accepted professional standards and applicable laws. Unused drugs and materials shall be disposed of in a manner so as not to endanger the public health.

13:39–10.15 Security

The sterile admixture area and its contents and other areas where drugs are stored shall be secured, so as to prevent access by unauthorized personnel.

SUBCHAPTER 11. STERILE ADMIXTURE SERVICES IN RETAIL PHARMACIES

13:39–11.1 Purpose and scope

This subchapter shall apply to all retail pharmacies which, on or after September 19, 1994, compound and dispense sterile admixture products, parenteral nutrition and/or parenteral drug therapy.

13:39–11.2 Training requirements

(a) The pharmacist in charge and the dispensing pharmacist shall have practical or academic training in sterile product compounding, clean room technology, laminar flow technology, and quality assurance techniques and shall be required to document such training if required by the Board.

(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. 13:39–11.8;

2. Familiarity with the necessary compounding techniques; and

3. Appropriate aseptic technique, which shall be proven by means of a test batch of growth-media.

(c) At least every six months, the pharmacist-in-charge shall test the aseptic technique of supportive personnel by means of a test batch of growth-media. Test results shall be recorded in a log which shall be available for the Board's inspection.

13:39–11.3 Supportive personnel; required supervision

(a) The dispensing pharmacist shall provide direct supervision to supportive personnel who are working within the controlled environment, as defined in N.J.A.C. 13:39–11.11. The dispensing pharmacist shall supervise, at any given time, no more than two supportive personnel performing delegated sterile admixture tasks.

1. For the purposes of this subchapter, "direct supervision" means that the dispensing pharmacist shall be present in the dispensing area whenever supportive personnel are compounding sterile admixture products, and shall conduct in-process and final 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 tasks set forth below in (c)2 (recording of the prescription, (c)3 (selection of the drugs, container and diluent), and (c)4 (compounding of sterile admixture) below. The dispensing pharmacist shall check that each task has been performed correctly prior to any further task being performed in the dispensing process.

13:39–11.4 Tracking document

(a) The pharmacist-in-charge and 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 dispensing pharmacist shall prepare a document to track completion of the following steps of the compounding process. The tracking document(s) shall be initialed by the individual(s) who completed each step:

1. Receipt of prescription;

2. Recording of prescription in the patient record profile system, pursuant to N.J.A.C. 13:39–11.10;

3. Correct selection of the drugs, container, and diluent prior to their being compounded in the clean room;

4. Verification that all sterile admixture compounding is performed within the 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 order;

6. Verification that the prescription label complies with the requirements of N.J.A.C. 13:39–11.5; and

7. Verification that the prescription order is complete and ready to be dispensed, including any necessary ancillary supplies.

(c) The completed tracking document(s) shall be kept in a separate file.

13:39–11.5 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 prepared;

2. The name of the physician;

3. The name of the patient;

4. Directions for use;

5. The name of the basic solution;

6. The name and amount 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, should the sterile admixture product contain any controlled dangerous substances;

10. The expiration date of the sterile admixture product;

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.

13:39–11.6 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.

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

13:39–11.7 Handling, packing and delivery

(a) 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. 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.

13:39–11.8 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 at least the following:

1. A risk-management program (including, but not limited to, incident reports, adverse drug reactions, and product contamination);

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;

4. Sanitation;

5. Reference materials;

6. Drug storage;

7. Drug dispensing;

8. Drug labeling;

9. Drug destruction and returns;

10. Delivery of drugs;

11. Patient recordkeeping;

12. Investigational new drugs; and

13. A quality assurance program.

(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.

13:39–11.9 Quality assurance program

(a) This section shall apply both to commercially available injectable drug products that are dispensed to patients without compounding or other manipulation, and to sterile admixture products that 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. The sterile admixture product is kept under appropriate controlled conditions at the location of use, and is administered through adequate labeling and verbal or written instructions;

2. The potency, pH, sterility, freedom from pyrogen, particulate limits, container integrity, appearance, and other qualities or characteristics that the sterile admixture product is expected to have do exist for the entire labeled life of the sterile admixture product, or until the sterile admixture product is manipulated by the patient or caregiver;

3. The quality assurance program encompasses every sterile admixture product under the pharmacy's control and includes all phases of its preparation, distribution, storage, administration, and directions for use;

4. The proper analytical testing is performed at regular intervals of time in order to verify the microbiological, chemical, and physical quality of all sterile admixture products;

5. Air and surface sampling takes place monthly;

6. Laminar air flow hoods are certified semi-annually;

7. The Class 1,000 Clean Room is certified semi-annually; and

8. 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).

13:39–11.10 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;

2. A complete record of the formulations of the sterile admixture products dispensed; and

3. Initial and ongoing clinical pharmacy monitoring plans.

(b) A reasonable, documented attempt shall be made to ensure that a patient profile record includes over-the-counter and home remedies.

13:39–11.11 Controlled environment: entry

(a) The pharmacy shall have designated areas, namely a clean room and an anteroom, which shall collectively be known as the controlled environment.

(b) The controlled environment shall be:

1. Accessible only to designated personnel;

2. Used only for the preparation of parenteral products, or such other tasks that require a controlled environment; and

3. Structurally isolated from other areas within the pharmacy by means of restricted entry or access.

13:39–11.12 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 sanitizing agents.

(c) Junctures of ceilings to walls shall be covered, caulked or sealed to avoid cracks and crevices where dirt can accumulate.

(d) Ceilings that consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic, and shall also be caulked around each perimeter to seal them to the support frame.

(e) 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) Dust-collection overhangs (such as ceiling utility pipes) or ledges (such as window sills) shall be either avoided or sealed.

(h) Ceiling lighting fixtures shall have exterior lens surfaces that are smooth, mounted flush, and air tight.

(i) Ceilings and walls shall have every penetration sealed.

13:39–11.13 Controlled environment: stocking

(a) The controlled environment shall contain only the following:

1. Items such as furniture, equipment, supplies, and other goods that are required for the tasks to be performed there;

2. Items that are nonpermeable, nonshedding, and resistant to disinfectants; and

3. Items that have been cleaned and sanitized just prior to their being enclosed.

(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.

13:39–11.14 Controlled environment: maintenance and supplies

(a) The controlled environment shall be kept clean and arranged in an orderly fashion. All required equipment shall be maintained in good operating condition.

(b) The controlled environment shall not be used for bulk storage, warehousing, or clerical and secretarial functions.

(c) 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.

13:39–11.15 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 conditions during normal activity shall be in place, such as laminar airflow hoods or the zonal laminar flow of high efficiency particulate air (HEPA) filtered air.

(e) The clean room shall contain the following equipment:

1. A laminar airflow hood or suitable HEPA filter system;

2. For the compounding and dispensing of antineoplastic agents, sufficient additional space to accommodate a vertical air laminar flow hood;

3. Waste containers in compliance with Occupational Safety and Health Administration (OSHA) standards for used needles and syringes, and for chemotherapy waste; and

4. Ancillary supplies required for proper compounding.

13:39–11.16 Anteroom

(a) The environmental quality within the anteroom shall be better in terms of demonstrated particle count or positive room pressurization than that of adjacent areas, such as the main pharmacy, so as to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the clean room.

(b) The anteroom shall contain the following equipment:

1. A sink with hot and cold running water;

2. Label and packaging equipment and supplies;

3. Waste containers for all personal protective equipment;

4. An eyewash station; and

5. A hazardous waste spill kit.

(c) A refrigerator, as required by USP 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.

(d) In addition to the minimum reference library mandated in N.J.A.C. 13:39–7.7, each sterile admixture service shall also contain the most current edition of the American Hospital Formulary Service and other reference materials pertinent to this specialized service.

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 reference books. All books must be current editions or revisions:

1. USP DI with supplements;

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.

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.